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# KOREAN HAND ACUPUNCTURE FOR PREGNANCY RELATED PELVIC GIRDLE PAIN: A FEASIBILITY STUDY

C E CLARKSON

PhD

2016

# KOREAN HAND ACUPUNCTURE FOR PREGNANCY RELATED PELVIC GIRDLE PAIN: A FEASIBILITY STUDY

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the requirements for Northumbria  
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Philosophy

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## Abstract

This thesis aimed to assess the feasibility of conducting a randomised controlled trial (RCT) into the use of Korean Hand Acupuncture (KHA) for pregnancy related pelvic girdle pain (PPGP). Despite PPGP developing in approximately 20% of all pregnant women, there are currently very few studies that have investigated interventional strategies, with a dearth of UK based studies. Of extant interventions investigated to date, acupuncture has shown some promising findings, although the effects of KHA on PPGP remain unclear. In line with the MRC framework for complex interventions, any potential treatment should be subjected to feasibility testing prior to a definitive RCT. This three phase feasibility study followed a mixed methods paradigm.

Phase 1 was a comparative study of 20 non pregnant women, measuring the belief that there had been a needle inserted into the skin, between a penetrating KHA (pKHA) group and a non-penetrating KHA (npKHA) group. Between group analysis found that at initial assessment ( $p=0.07$ ) and one week post intervention ( $p=0.643$ ), believability was similar. Qualitative comments were analysed through content analysis, and provided insight into what factors influenced their belief score, such as 'acupuncture noises'. The study findings helped to develop the intervention protocol in Phase 3. This study was the first to investigate the believability of a non penetrating form of KHA.

Phase 2 recruited eight PPGP sufferers and adopted a qualitative approach, using semi-structured interviews to gain an understanding of how PPGP affected them. Data was subjected to thematic analysis and produced four themes: The reality of PPGP; Support mechanisms most important in PPGP; Vulnerability and; Knowledge is power. Findings indicated PPGP is a problem that is biopsychosocial, and one which is represented via the Pelvic Girdle Questionnaire (PGQ). It demonstrated that information provision was considered as important to the participants within this study as it is to sufferers outside of the UK, and that they valued health care professional advice and support. This is the first UK based study to investigate women's experience of PPGP, the first piece of qualitative work with the lead author and interviewer being male, the first to provide a level of validity to PGQ use within the UK and the first to adopt a pragmatic philosophy.

Phase 3 was a mixed methods feasibility study, assessing the acceptability and practicality of conducting a definitive RCT on KHA for PPGP. A two armed study consisting of six sessions in either a standard physiotherapy plus pKHA or a standard physiotherapy plus npKHA group. The study recruited 59 women, 40 of whom completed all six sessions. Acceptability and practicality was confirmed through content analysis of the qualitative data produced by the participants, in particular those in the pKHA group who stated they would seek out the treatment again. Further acceptability was noted as all adverse events experienced were minor and transient, and that the retention of women to the study was greater than normally expected from the study population. In addition, trends noted in NRS at present ( $p=0.002$ ) and PGQ ( $p=0.041$ ) at the final data point indicated that pKHA may have additional benefits over npKHA for PPGP. The original contributions from Phase 3 are that it is the first study to be conducted using KHA for a pregnancy related condition in the English language and the first study to adopt a mixed methods approach within the UK for an acupuncture study within pregnancy. Finally, it is the first study written in English that has compared pKHA to npKHA for any condition.

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## List of Abbreviations

ACPWH	Association of Chartered Physiotherapists in Women's Health
ADL	Activity of Daily Living
ANOVA	ANalysis Of VAriance
ASLR	Active Straight Leg Raise
BMI	Body Mass Index
CAM	Complementary and Alternative Medicine
CI	Chief Investigator
CLBP	Chronic Low Back Pain
CNS	Central Nervous System
CONSORT	CONsolidated Standards Of Reporting Trials
DNA	Did Not Attend
DNIC	Diffuse Noxious Inhibitory Control
DRI	Disability Rating Index
EQ-5D	EuroQol 5 Dimensions Questionnaire
FABERs	Flexion ABduction External Rotation test
fMRI	functional Magnetic Resonance Imaging
HRQL	Health Related Quality of Life
KHA	Korean Hand Acupuncture
LBP	Low Back Pain
LBPp	Low Back Pain in pregnancy
MMR	Mixed Methods Research
MRC	Medical Research Council
MSK	Musculoskeletal
N/A	Not Applicable
NHS	National Health Service
NICE	National Institute for Clinical Excellence
npKHA	non-penetrating Korean Hand Acupuncture
NRES	North east Research Ethics
NRS	Numerical Rating Scale
NSAID	Non-Steroidal Anti Inflammatory (drug)
ODI	Oswestry Disability Index



## List of Abbreviations

ONS	Office of National Statistics
P4	Posterior Pelvic Pain Provocation test
PEDro	Physiotherapy Evidence Database
PGP	Pelvic Girdle Pain
PGQ	Pelvic Girdle Questionnaire
PIS	Participant Information Sheet
POGP	the Pelvic Obstetrics and Gynecology Physiotherapy group
PPGP	Pregnancy related Pelvic Girdle Pain
pKHA	penetrating Korean Hand Acupuncture
ppPPGP	post-partum Pregnancy related Pelvic Girdle Pain
QoL	Quality of Life
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised Control Trial
RMDQ	Roland Morris Disability Questionnaire
RVI	Royal Victoria Infirmary
SC	Standard Care
SF-36	Short Form 36
SF-MPQ	Short Form McGill Pain Questionnaire
SIJ	Sacro Iliac Joint
SP	Standard Physiotherapy
STRICTA	revised STandards for Reporting Interventions in Clinical Trials of Acupuncture
TCM	Traditional Chinese Medicine
UK	United Kingdom
VAS	Visual Analogue Scale

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## **Declaration**

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my own work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others.

Any ethical clearance for the research presented in this thesis has been approved. Approval has been sought and granted by the Northumbria University ethics panel (Reference number RE-HLS-12-130701-51d1815248c3f) on 7th August 2013 for the study outlined in Chapter 5. Approval has been sought and granted for studies conducted in Chapter 6 and 7 by the Faculty of Health and Life Sciences Research Ethics Review Panel 24th October, 2013, ref. number: RE-HLS-12-130701-51d1815248c3f. It was then passed for ethical approval via Newcastle and North Tyneside 1 NRES Committee 2.4.2014, reference number 14/NE/0060, 7th April 2014.

I declare that the Word Count of this Thesis is 68,337 words

Name: Carl Clarkson

Signature:

Date:

# Chapter 1

## Introduction

### 1.1 Introduction

Pregnancy related pelvic girdle pain (PPGP) is a condition which affects between 10% (Brown and Johnston, 2013) and 84% (Bastiaanssen *et al.* 2005) of pregnant women, although a recent Cochrane review by Pennick and Liddle (2013) suggested its prevalence is likely to be around 20%. The Vleeming *et al.* (2008, p.797) definition of PPGP is consistently put forward, and reads: ‘...(it) generally arises in relation to pregnancy, trauma and/or osteoarthritis. The pain can be located anywhere around the pelvic girdle, more specifically around the posterior iliac crest and gluteal folds, and/or radiating to the posterior thigh and to include pain around the symphysis’. However, this is devoid of any psychosocial context, and actually refers to pelvic girdle pain (PGP) in any population, not specific to pregnancy. Ostgaard *et al.* (1994) put forward an argument for PPGP to be considered as a separate entity to low back pain in pregnancy (LBPp), after they found clinical tests could be performed to differentiate between the two. Wu *et al.* (2004), in their systematic review, considered that there is enough evidence to support the separation of LBPp and PPGP in research terms, although they acknowledge that both can, and often do, appear synonymously.

It would appear from existing literature that PPGP produces pain (Wu *et al.* 2004) and restriction to activities of daily living (ADL) (Rost *et al.* 2004). In addition, researchers have discussed the impact of PPGP on quality of life (Elden, Lundgren and Robertson, 2013), fear (Fredriksen, Moland and Sunby, 2008) and social interactions (Elden, Lundgren and Robertson, 2013). It would also seem that PPGP can remain post pregnancy, impacting upon the woman and behaving as a chronic condition (Stuge *et al.*

2004). This provides a strong rationale to investigate PPGP, not only in terms of how it affects the PPGP sufferer in the UK, but to also explore avenues for potential treatment. Pham (2014) put forward the notion of over caution in pregnancy by researchers, clinicians and patients, stemming from serious adverse events that occurred from drug trials in the 1950's and 1960's. This has culminated in a general reluctance, and therefore paucity, of research for interventions treating pregnancy related conditions, and more specifically, PPGP.

A recent systematic review by Clarkson, O'Mahony and Jones (2015) indicated that acupuncture is safe to administer during pregnancy. Overall, it was found adverse event reporting to be poor on several counts. Out of the 25 studies identified as being eligible, 17 remained in the final analysis due to eight not mentioning adverse events at all. Of those studies that were included, only two provided adequate amount of description to allow for accurate incidence rates to be calculated (Clarkson, O'Mahony and Jones, 2015). It was also noted that some studies reported effects that would likely be perceived as beneficial, or at the very worst not perceived as negative, as adverse events. To address the quality of reporting, the authors suggested that researchers not only conform to CONSORT guidelines by Ioannidis *et al.* (2004), but provide additional information to allow the reader a better understanding of the frequency of adverse events. Finally, taking into account the poor quality of reporting, the trend for adverse event occurrence was very similar in penetrating acupuncture and non-penetrating intervention groups, and the adverse events that did occur were largely minor and transient (Clarkson, O'Mahony and Jones, 2015). This lends credibility to investigating acupuncture in pregnancy, though due to small numbers within the systematic review, continued monitoring and reporting should be continued. In addition, decisions on treatment should not be made outside of

the context of potential benefits, with several studies investigating acupuncture effectiveness for PPGP.

For over 2000 years, acupuncture has been administered as a treatment for a host of conditions, with its origins likely from ancient China (Hopwood, 2004). Although acupuncture can adopt many forms, it is defined as “piercing of the skin with a fine needle” (Roschke *et al.* 2000, p.73). The Traditional Chinese Medicine (TCM) approach is the most commonly used, with clinicians needling acupoints which are found throughout the body. These acupoints are thought, in TCM practice, to be located on meridians, and are needled when a person has pain or ill health. Pennick and Liddle (2013) and Gutke *et al.* (2015) recognised acupuncture as an approach with a promising evidence base for PPGP. Although researchers such as Wedenberg, Moen and Norling (2000) and Da Silva *et al.* (2004) have found acupuncture to be effective when compared to a control group, they lacked sufficient methodological quality upon which to base clinical practice.

Higher quality studies by Elden *et al.* (2005), Elden *et al.* (2008) and Wang *et al.* (2009) have also yielded promising results, yet they too have some areas upon which reliability could be improved. Additionally, the type of acupuncture best suited to PPGP management is yet to be established, with authors such as Elden *et al.* (2008) opting for a body acupuncture approach, whereas Wang *et al.* (2009) used an auricular acupuncture approach. As PPGP would seem to be aggravated by moving from static positions (Stuge *et al.* 2011), further investigation into non-body acupuncture methods are warranted. Korean Hand Acupuncture (KHA) is one such approach, and has found favour with many acupuncturists worldwide (Kim *et al.* 2005). It works on the theory that each hand represents 14 ‘micro meridians’ and, therefore, each body acupuncture point used in TCM can

be found and represented as an acupoint on the hand (Yoo, 2001). Korean Hand Acupuncture is an intervention that has not been investigated within a pregnant population, and thus advocated its investigation within a PPGP population.

To date, there have been no published studies specifically investigating the impact of acupuncture upon PPGP which have been conducted in the UK, and thus the need for further high quality research that can be applied to the UK population is required. To do this, the Medical Research Council (MRC) framework on complex interventions (Craig *et al.* 2008) have been considered as an underpinning framework on which to base this thesis. The MRC framework (Craig *et al.* 2008) highlights that evaluation of complex health interventions is often undermined by poor compliance, delivery of the intervention, recruitment and retention, and smaller than expected sample sizes, all of which can be measured by first adopting a feasibility study. The MRC put forward a 'development-evaluation-implementation process' (Craig *et al.*, 2008), suggesting a complex intervention should be subjected to numerous activities on its journey from development to implementation. These are:

1. Development
2. Feasibility/piloting
3. Evaluation
4. Implementation

In order to prevent undermining any future definitive randomised controlled trial (RCT), thorough feasibility investigation was warranted before evaluating KHA effect on PPGP. The literature reviewed in Chapters 2 and 3, and investigation of stakeholder views via a qualitative approach (Chapter 6) all can be considered as part of the development phase

in line with the MRC framework. The feasibility phase, as identified by Craig *et al.* (2008) as an imperative prelude to any RCT, was attended to through testing of the KHA process and procedure (Chapter 5), before being implemented in a PPGP population (Chapter 7). This involved investigating: the refinement of the KHA procedure; recruitment and retention; suitability of the outcome measures and; acceptability of the study. Finally, the discussion at the end of each empirical study conducted as part of this thesis (Chapters 5-7), as well as the overall discussion (Chapter 8), begins to perform an evaluation of KHA.

Therefore, given that PPGP has been under researched within a UK population, and that KHA has no published literature in the English language in a pregnancy related condition, it was considered essential that a feasibility study be conducted. To achieve this, a mixed methods research approach was adopted over three empirical phases, using both quantitative and qualitative methods, to establish whether KHA for PPGP is feasible to investigate in a definitive RCT. Therefore, the overall aims of this feasibility study are:

1. To develop a believable non-penetrating Korean Hand Acupuncture (npKHA) approach
2. To measure acceptability of both npKHA and pKHA through participant retention and adverse events experienced in a non-pregnant, female population
3. To gain an understanding of PPGP as experienced by women in the UK
4. To develop and implement a study investigating the practicalities of delivering KHA for PPGP



This thesis will achieve its aims through an eight Chapter discussion and synthesis of current published literature combined with empirical research, conducted by the researcher. To begin, Chapter 2 defines PPGP and why it is relevant to this thesis, exposing the need for further research within the UK.

Following the discussion around the relevance of PPGP, a detailed consideration of current intervention strategies that are used to help PPGP sufferers is discussed (Chapter 3), with particular focus upon physiotherapy and acupuncture. This will display to the reader an understanding and rationale of why acupuncture is an important therapeutic tool to use within PPGP, and where the original contribution to knowledge will be put forward in subsequent chapters. A detailed rationale is then provided for the use of a mixed methods approach to investigating PPGP in Chapter 4, providing both a philosophical stand point and evidence of its acceptance as an appropriate method for health care research involving acupuncture. The MRC framework is also discussed, and how it relates closely to a mixed methods paradigm. This chapter then leads into the three empirical studies conducted over a two year period, in which the PhD student was the Chief Investigator (CI), data collector and conducted the analysis. Chapters 5 (Phase 1) and 6 (Phase 2) were independent of each other, acting as standalone studies. Phase 1 investigated the believability of a non-penetrating approach to KHA within a non-pregnant population, whereas Phase 2 explored PPGP sufferers' views on the condition. However, as will be outlined below, they both informed the study methods conducted in Chapter 7 (Phase 3), which aimed to investigate the feasibility of executing an intervention protocol for KHA in PPGP.

The mixed methods approach adopted in this thesis demonstrates how quantitative and qualitative research can work in tandem. Importantly, it will be observed that the studies

investigating the feasibility of KHA (reported in Chapter 5 and 7), which are primarily quantitative, also collected qualitative data to help to provide context and better understanding of the effects observed. For example, within Chapter 5, participants were given either penetrating KHA (pKHA) or non-penetrating KHA (npKHA), and then asked to rate how confident they were that they had received pKHA on a Likert type item. This is supported by qualitative data, whereby each participant was asked why they felt they either did or did not have pKHA. The results for the Likert type item and qualitative comments are combined within the discussion passage at the end of Chapter 5, and informed the study procedure comparing pKHA and npKHA with a PPGP population in Chapter 7. The findings demonstrate an original contribution to knowledge, as it is the first study to investigate the believability of an npKHA approach used solely on the dorsum of the hand.

The qualitative based phase representing the views and experience of stakeholders, presented in Chapter 6, can be considered a standalone piece of research. However, it also helped to inform the final phase, presented in Chapter 7, which was a feasibility study investigating pKHA vs npKHA in PPGP sufferers. Semi-structured interviews with eight PPGP sufferers, explored stakeholders views on the condition. There were a number of similarities with existing qualitative studies, such as information provision, importance of support networks and symptoms experienced. However, the findings produced from this chapter demonstrate originality through it being the first UK based exploration of PPGP sufferers views, providing discussion around interviewee's expectations of treatment, being the first to adopt a pragmatic philosophy in PPGP views, expressing views of PPGP sufferers upon the Pelvic Girdle Questionnaire (PGQ), and being the first exploration of views on PPGP by a male lead author. The results of this chapter also informed the feasibility study displayed in Chapter 7.

The aim of the final phase was to investigate the feasibility of executing an intervention protocol for KHA in PPGP. A number of studies exist that have investigated acupuncture for PPGP. However, most either record low on quality scores via PEDro (Wedenberg, Moen and Norling, 2000; Kvorning *et al.* 2004; Da Silva *et al.*, 2004), or have looked at effects over a short time frame (Wang *et al.* 2009). Elden *et al.* (2005) and Elden *et al.* (2008) are considered more robust experiments, and thus lead a Cochrane review by Pennick and Liddle (2013) to stipulate that acupuncture could be a useful intervention for PPGP. However, higher quality work is needed (Pennick and Liddle, 2013), and UK based research investigating acupuncture for PPGP is absent. In addition, the method of best practice is yet to be established, with Elden *et al.* (2005) and Elden *et al.* (2008) opting for body acupuncture styles, whereas Wang *et al.* (2009) opted for a micro meridian approach. The use of a micro meridian system, such as KHA, that does not require the participant to remain in a static position, may prove to be beneficial to PPGP sufferers, and may be a more accepted approach by those physiotherapists reluctant to use acupuncture.

Over one third of physiotherapists who use acupuncture in pregnancy use points on the hand (Bishop *et al.* 2015), and so KHA would likely be acceptable to those who use these acupoints. However, in order for any definitive RCT, which may follow this feasibility study, to be comparable to existing literature, the outcome measures adopted must be similar. Elden *et al.* (2008) and Wang *et al.* (2009) both measured pain and function, and therefore the study conducted in Chapter 7 used outcomes for pain via the Numerical Rating Scale (NRS), and function through the Pelvic Girdle Questionnaire (PGQ). Credibility of pKHA and npKHA (via a credibility scale) was also measured, as Wang *et al.* (2009) and Elden *et al.* (2008) considered it important, with the credibility scale supported by qualitative data on what participants' views on the study were (via an end of

study questionnaire). In addition, qualitative data was collected on treatment effects to capture any adverse events or benefits to treatment, that would be otherwise missed from data collection through only using the NRS, PGQ and credibility scales.

The original contributions from Phase 3 are that it is the first study to be conducted using KHA for a pregnancy related condition in the English language and the first study to adopt a mixed methods approach within the UK for an acupuncture study within pregnancy. It is also the first study written in English that has compared pKHA to npKHA for any condition. Finally, Chapter 8 serves to synthesise the whole PhD, providing conclusions upon the findings throughout this thesis, highlighting original contributions to knowledge, limitations of the research conducted and providing suggestions for future research into PPGP.

## **Chapter 2**

### **Pregnancy related Pelvic Girdle Pain: Background**

A literature search pertaining to pregnancy related pelvic girdle pain was conducted via databases AMED, CINAHL, EMBASE, MEDLINE and PubMed. Search terms included: “Pregnancy related Pelvic Girdle Pain”, “Pregnancy related low back pain”, “Pelvic Pain”, “Pregnan\* AND pain”, “Symphysis Pubis”, “Symphysis Pubis Syndrome”. MESH headings were used when available. Reference lists of relevant publications were also searched. Only publications that were written in English were included, with title and abstract reading performed to ascertain the appropriateness of the study for this chapter.

#### **2.1 Defining PPGP**

There are numerous causes of pain around the pelvis, with dysfunctional uro-genital and reproductive organs, previous traumatic experiences, sexual abuse, and musculoskeletal type pain all potential instigators (Chaitow and Jones, 2011). Those conditions that are thought to originate from a specific organ or event are usually diagnosed as a specific syndrome, for example ‘bladder pain syndrome’ (Chaitow and Jones, 2011). These specific conditions, whether as a cause of infection, inflammation, or trauma, are usually dealt with by specialists in the area. One such condition, pelvic girdle pain (PGP), affects a considerable number of men and women, and is synonymous with perceived difficulty in achieving positive treatment outcomes (Vleeming *et al.* 2008). This is not to be confused with pelvic pain syndrome, whereby persistent or episodic pelvic pain is thought to be due to urinary, bowel, gynaecological or sexual organ dysfunction (Chaitow and Jones, 2011).

Pelvic girdle pain is thought to be musculoskeletal in origin and has both physical and psychosocial factors which heavily influence its presence, severity and prognosis (Pennick and Liddle, 2013). This has led some authors, such as Chaitow and Lovegrove (2011) to suggest that PGP is not a diagnosis, but more a definition. Vleeming *et al.* (2008, p.797), in their European guidelines for pelvic girdle pain, define it as 'generally arises in relation to pregnancy, trauma and/or osteoarthritis. The pain can be located anywhere around the pelvic girdle, more specifically around the posterior iliac crest and gluteal folds, and/or radiating to the posterior thigh and to include pain around the symphysis'. What is striking about this definition is its focus upon the physical locality of the pain, and ignoring the broader impacts and potentially identifiable characteristics of PGP identified by Chaitow and Lovegrove (2011).

Several authors have put forward abbreviations/terminology to describe PGP during pregnancy, though Pregnancy related Pelvic Girdle Pain (PPGP) seems to be the preferred option for most researchers (Wu *et al.* 2004; Gutke *et al.* 2015). Historically, the definition of PPGP, and recognition of it as an outright entity, has taken until Osgaard *et al.* (1994) put forward their findings, demonstrating that clinical tests could be performed to differentiate between PPGP and Low Back Pain in pregnancy (LBPp). Previously, PPGP has been viewed as either an extension of LBPp, or sub divided into various syndromes such as Symphysis Pubis disorder or Sacro Iliac Joint (SIJ) dysfunction (Wu *et al.* 2004). These sub-divisions are usually helpful for the therapist to help determine what treatment is best advocated (Verstraete, Vanderstraeten and Parewick, 2013). However SIJ dysfunctions, Symphysis Pubis disorder and LBPp, can be encompassed under the umbrella term of PPGP (Wu *et al.* 2004). As such most research has either; investigated LBPp to encompass pain in the pelvic girdle, looked at a specific subset of PPGP, and/or

used outcome measures not validated for PPGP. However, Wu *et al.* (2004), in their systematic review discussing pain in the lumbar spine and pelvis, suggested that there is enough research to advocate the adoption of PPGP as a condition separate to others, though it can occur synonymously with LBPp. Therefore, it is suggested here that the definition provided by Vleeming *et al.* (2008), and the consideration of PPGP as a purely musculoskeletal issue, does not accurately reflect the complex neuromatrix that influences pain perception. Therefore this thesis will propose a more appropriate definition for PPGP on the basis of current literature surrounding PPGP and findings from Chapter's 6 and 7.

## **2.2 The diagnosis of PPGP**

The consensus within the literature is that PPGP has a definite musculoskeletal (MSK) component, and as such should be diagnosed primarily through subjective questioning and clinical tests such as those outlined in Table 1 (Vleeming *et al.* 2008; Pennick and Liddle, 2013). This leads clinicians to believe that if specific aggravating factors associated with movement can be identified, it is most likely to originate from the musculoskeletal system (Chaitow and Lovegrove, 2011). According to Kanakaris, Roberts and Giannoudis (2011), the most reliable pain provocation tests are the Posterior Pelvic Pain Provocation (P4) test, the Flexion Abduction External Rotation (FABER's) test, Active Straight Leg Raise (ASLR), Gaenslen tests, Trendelenburg and deep palpation of Pubic Symphysis, with the authors recommending a combination of these to help minimise false negatives due to the low sensitivity of each of these tests as a single entity. Olsen, Elden and Gutke (2014) supported the approach of multiple tests to give stronger support to diagnosis, although they advocated the P4, FABERS, Trendelenburg, pulling a mat with the foot (MAT test), ASLR, palpation of the Pubic Symphysis, and additionally, the bridging test. However, Vleeming *et al.* (2008) put forward that there is currently no

consensus on which of these tests clinicians should choose, with Pennick and Liddle (2013) pointing out that the internal validity and reliability of the classification of PPGP remains questionable because of the wide range of ways to diagnose it. Therefore, because no gold standard test has been identified, different studies have used different approaches to diagnose PPGP.

Authors such as Bjelland *et al.* (2013) have solely relied upon patients reporting pain in the pelvic region as the diagnostic factor. Others, such as Mogren and Pohjanen (2005) have classified PPGP as pain in the lumbo pelvic region, failing to differentiate between LBPp and PPGP despite Osgaard *et al.*'s. (1994) work. Even those who advocate multiple tests to diagnose PPGP, such as Kanakaris, Roberts and Giannoudis (2011) and Olsen, Elden and Gutke (2014), recommend different tests to classify PPGP. This creates difficulty for study comparison and generalisability of results produced, and in combination with the previously discussed issue with PPGP definition, advocates the need for more work on PPGP. Despite the above discrepancies, all authors seem to be in agreement that in order for PPGP to be diagnosed, women should report pain in the pelvic girdle region that increases with functional movements such as sit to stand, walking, or sitting/standing for long periods (Kanakaris, Roberts and Giannoudis, 2011; Vleeming *et al.* 2008).



**Table 1 Clinical tests performed to identify PPGP**

Test name	Full Name
ASLR	Active Straight Leg Raise
FABER	Flexion Abduction External Rotation
P4	Posterior Pelvic Pain Provocation test
Trendelenburg	Trendelenburg test
Gaenslen test	Gaenslen test
Deep palpation of pubic symphysis	Deep palpation of pubic symphysis
Bridging test	Bridging test
MAT test	Pulling a mat with the foot

### **2.3 The symptoms and impact of PPGP**

Wu *et al.* (2004) found that pain in PPGP was most commonly reported between 50mm and 60mm on a Visual Analogue Scale (VAS), but with the upper quartile of women reporting it as 90mm, suggesting 25% of women affected by PPGP suffer with extreme pain. Elden, Lundgren and Robertson (2014a) conducted 27 in-depth interviews, using a content thematic analysis, with women who were deemed to have severe PPGP. This was part of a mixed methods approach, although no further reference is made to any other part of the study, it being published as a purely qualitative piece. The authors aimed to explore and describe women's experiences of pelvic pain and discussed four main themes: a strange body, the body on guard, support from health care, and ac-

ceptance of PPGP. The intensity of pain was described by some women as 'pain dominating their entire existence' (Elden, Lundgren and Robertson, 2014a), and is supported by their earlier qualitative study (Elden, Lundgren and Robertson, 2013), who found pain to be a prominent factor in women's PPGP. In addition, Kvorning *et al.* (2004) and Da Silva *et al.* (2004) present findings, discussed in depth in Chapter 3, that suggest that PPGP becomes worse as pregnancy develops, and symptoms may also persist post pregnancy if left untreated (Rost *et al.* 2006). However, several studies have identified that PPGP also impacts upon Activities of Daily Living (ADL), such as Rost *et al.* (2004) who conducted a study to identify symptoms of PPGP through 870 women in the Netherlands.

Participants in the Rost *et al.* (2004) study were considered to have PPGP if they reported pain in the pelvic region, on ASLR, on palpation of pelvic joints, and on a FABER's test. They found that although women did not report continuous pain, it was aggravated by changes of position and ADL, usually within 30 minutes of beginning a task such as walking. The authors also found that 1% used crutches and 1% used a wheelchair, though it is unclear whether this was due to PPGP. Elden, Lundgren and Robertson (2014a) also reported difficulties in walking, and that there was anxiety in not being able to change positions as they moved closer to delivery. Significantly, no literature can be found that refutes that ADL's are impacted negatively by PPGP. Finally, Stuge *et al.* (2011) produced an outcome measure, the first that is PPGP specific, that looks to measure the impact of PPGP on ADL's (Appendix 1). The Pelvic Girdle Questionnaire (PGQ), which was produced as a result of clinical experience in dealing with PPGP, and on the back of numerous focus groups with women who had experienced PPGP, is a Likert scale which helps identify the severity in which ADL's are effected by PPGP (Stuge *et al.* 2011). A subsequent analysis by Grotle *et al.* (2012) demonstrated that the

PGQ was both valid and reliable for measuring the impact of PPGP on ADL's, and will be discussed in detail later in this chapter. In combination with the aforementioned studies highlighting pain intensity, the production of the PGQ highlights that PPGP is a condition which impacts upon ADL's, and thus advocates investigation into potential treatments such as KHA.

In addition to impacts on ADL's, Vermani, Mittal and Weeks (2010) put forward that other indicators of reduced Quality of Life (QoL) exist such as socioeconomic impacts. The social impacts of PPGP have been discussed in several qualitative studies, with Elden, Lundgren and Robertson (2014a) finding that women felt 'cheated' and 'feel you're on your own' due to PPGP being such a prominent feature of their pregnancy. Elden, Lundgren and Robertson (2013) conducted a descriptive study as part of a mixed methods approach for cranial sacral therapy in PPGP, with 27 women. They used content thematic analysis, with two of the authors independently analysing the data. The authors provided an adequate description of how they arrived at their final five emerged themes, using constant comparison throughout all transcripts. They found that the social life of PPGP sufferers had been severely restricted as they could not meet up with people as they had done previously, and that it was noted that having a good social network was considered extremely valuable. Further common comments made surrounded perceptions that others had of them, and how they tended to spend more time with 'friends who understood their situation.' This extended into the workplace, where women commented upon how employers could be either supportive or not understanding PPGP at all (Elden, Lundgren and Robertson, 2013). The respondents also expressed further concerns around their relationship with existing children and their partner, finding that both had changed quite dramatically because they could not do what they used to.

In the only existing qualitative study looking at the impact of PPGP on the male partner, Elden, Lundgren and Robertson (2014b) found that emotional strain from PPGP extended to men as it impacted upon their social life, but more importantly meant that they felt they could not talk about the way they felt because the 'woman was going through the worst of it.' Persson *et al.* (2013) also found that their respondents gave particular emphasis on the importance of psychological support from their family and close friends, and Elden, Lundgren and Robertson (2013) extended this further to suggest supportive partners were considered a real benefit, whilst other participants could see how PPGP could lead to a relationship breakdown. As will be discussed later within this chapter, PPGP may be impacted upon by social factors, and because there is currently no qualitative literature investigating PPGP sufferers views from the UK, Chapter 6 explored whether social impacts were observed.

Financial burden was also given special mention by Elden, Lundgren and Robertson (2014a) as 'women reported how they worried about the [state] not approving sick leave.' In support of these findings, the same authors discussed this as a problem when they interviewed male partners about the impact of PPGP on their lives (Elden, Lundgren and Robertson, 2014b). Further to this, a qualitative study with nine PPGP sufferers by Persson *et al.* (2013) found that eventually all women had to take sick leave from their employment. The method of data collection, analysis and synthesis was clear (adopting thematic analysis), displaying their results via overarching themes and the smaller categories that contributed to the creation of each theme. The latter authors also provided a reflexive account, allowing the reader to gain an appreciation of their warranted beliefs and, therefore, helping to understand how the data presentation may have been influenced. The authors highlight the issue surrounding terminology which impacts upon a woman gaining sick leave and that, in Sweden, as PPGP is considered a normal part of

pregnancy, a woman would not be automatically granted sick leave. This adds to literature by Elden, Lundgren and Robertson (2013) and Elden, Lundgren and Robertson (2014b), suggesting that this Swedish viewpoint on PPGP gives rise to further anxieties surrounding the compassion the state shows to these women, and that the state/medical profession considers PPGP as a mere minor consequence of pregnancy. It could therefore mean individuals exaggerate PPGP symptoms in order to gain sick leave. However, this has yet to be identified whether this exists in other cultures such as in the UK, and will therefore be explored through semi structured interviews in Chapter 6.

One study by Olsson *et al.* (2004) looked at health related quality of life (HRQL) in relation to LBP; HRQL was found to be worse in late pregnancy and in pregnant women experiencing LBP compared with non-pregnant healthy women. During normal pregnancy, wellbeing can be affected by a number of factors including nausea (Broussard and Richter, 1998), sleep disturbances (Ross and McLean, 2006) and LBP (Elden *et al.* 2008). In the qualitative study by Elden, Lundgren and Robertson (2013) interviewing pregnant women with PPGP, the participants pointed out that it left them with ‘....a feeling of tiredness that you can’t get rid of’ attributable to the lack of sleep they had due to PPGP. The authors later suggested that PPGP dominated the woman’s whole existence, with physical symptoms being accompanied by psychological impacts (Elden, Lundgren and Robertson, 2014a).

In a study by Olsson *et al.* (2012), questionnaires were completed at 19-21 weeks gestation by 324 women and again six months post-partum (273 responses) in order to evaluate potential determinants of self-reported lumbopelvic pain. Measurements included The Pain Catastrophising Scale (used to gauge the extent of exaggerated negative thoughts about pain), the Fear-Avoidance Beliefs questionnaire (to measure the extent

to which physical activity is affected by pain), the VAS (to assess pain intensity), the Disability Rating Index (to determine physical ability) and the Nottingham Health Profile (to assess HRQL). Of the 273 who answered on both occasions, 112 reported lumbopelvic pain. Women who presented with PPGP/LBPp, physical restrictions or had a tendency for catastrophising were around double the risk for persisting with post-partum lumbopelvic pain. Nineteen percent of women with severe LBP during pregnancy elected not to become pregnant again due to the fear of LBP reoccurring, indicating a degree of fear for the future (Bastiaanssen *et al.* 2005). However, much of the literature on the psychosocial aspect of PPGP has been through a qualitative paradigm.

Mogren, Winkvist and Dahlgren (2010) explored 10 Swedish midwives' views on PPGP, adopting one to one interviews with a follow up focus group process to collect data. As with all small scale research, it would be wholly inaccurate to present this work as generalisable to the wider population of midwives, something which the authors themselves stress. It is rare for the aim of qualitative research to achieve generalisability (usually reserved for quantitative research). The authors used content thematic analysis for their data interpretation and analysis to attempt to improve understanding of the interaction between midwives and pregnant women with PPGP. However content analysis is often considered a superficial form of data analysis (Carpenter and Suto, 2008) and so could be considered a weakness to the study findings. Mogren, Winkvist and Dahlgren (2010) documented their reflexivity, and provided triangulation through a follow up focus group, with well organised interviews and a moderator present, all of which are considered strengths to qualitative research (Carpenter and Suto, 2008). They found that midwives thought having pelvic pain influenced the mood of the pregnant woman 'and make them downhearted'.

In support of these findings, Elden, Lundgren and Robertson (2013) and Perrsson *et al.* (2013), who interviewed women with PPGP, also found that emotional distress was commonly reported. A subcategory of Elden, Lundgren and Robertson (2014a), 'uncertain of your own feelings', highlighted women reported being 'frustrated, moody, close to tears and quick to complain', with being unhappy leading to a feeling of guilt. The findings from this study provide the reader with a better understanding of how PPGP affects the pregnant woman, beyond what can be captured from an objective measure. This advocates further research into what symptoms are experienced by PPGP in UK sufferers, providing further rationale for the qualitative study in Chapter 6.

Further findings from Mogren, Winkvist and Dahlgren (2010) indicated a level of power that healthcare professionals can exert upon their patients. The midwives in this study reported an increasing prevalence of PPGP, and suggested that this was due to it being more in the public domain, leading to more women self-diagnosing. This led to one emerging theme of a mutual mistrust, between the midwife and the pregnant woman. This was mainly apparent when symptoms described did not follow usual symptom patterns of PPGP, although the midwives felt that the level of mistrust was not considered as a major problem (Mogren, Winkvist and Dahlgren, 2010). This could mean that patients were not offered healthcare provision if the midwife did not believe the patient had PPGP.

The theme of health professional impact upon the PPGP sufferer is developed further by Wellock and Crichton (2007), who looked at 28 UK women's experiences of care offered via individual interviews. The authors adopted a phenomenological Heideggerian approach as they felt that their experiences as midwives could enrich the data analysis, ra-

ther than detract from it. They provided an attempt at triangulation by repeating their interviews with the same women at three separate points. However, on reflection of the difficulty of keeping participants involved in a trial, only three women repeated the interviews all three times, with eight only being interviewed once. Despite the lack of women who gave three interviews, the fact that 20 of the 28 in total provided more than one interview gives the results presented more credibility. However, the methods adopted were poorly reported, meaning that transparency and thus trustworthiness of the research is reduced. In fact, lack of detailed reporting is considered a flaw in many published qualitative articles (Patton, 2002; Morgan, 2014).

Many of the women interviewed by Wellock and Crichton (2007) spoke about how they were well supported by their midwife, although some negative experiences were also reported. Interestingly, positive interactions were reported with physiotherapists, a reoccurring reason being that a label was given to their pain. The authors concluded 'there can be no doubt that labeling the condition does help since this can validate the pain' (Wellock and Crichton, 2007). This is in stark contrast to Mogren, Winkvist and Dahlgren (2010) midwives, and therefore suggests that information provision on what PPGP is plays a larger role in positive perception of healthcare input than is given credit for. However, there is an indication that the lack of information provided by midwives on PPGP is not limited to Sweden, and that it may also be apparent in the UK.

The women in the study by Wellock and Crichton (2007) stated that they were 'shocked by the pain they experienced, it was so unexpected' suggesting information provision was not always timely. In accordance with the findings and suggestions made in Mogren, Winkvist and Dahlgren (2010) and Wellock and Crichton (2007), Elden, Lundgren and Robertson (2014a) found women most appreciated doctors with knowledge of PPGP



and who did not treat the problem lightly. 'To be acknowledged by the midwife' was a subcategory, which expressed that if the woman 'had a good relationship with their midwife', there was a feeling of being safe. Conversely, the midwife-patient relationship was not always optimum and thus led women to 'take initiative themselves and actively seek support.' There was also a belief that PPGP sufferer's symptoms had not been taken seriously by health givers in a study by Fredriksen, Moland and Sunby (2008), something which could also be interpreted by Mogren, Winkvist and Dahlgren (2010) findings on midwives' views.

One criticism of qualitative methods is that because data collection is often done in face to face scenarios, the types of conversation participants have may be influenced by their feeling of wanting to give the researcher what they think they are looking for (Carpenter and Suto, 2008). So, an approach whereby data are not collected in this manner may provide a different insight, something which Fredriksen, Moland and Sunby (2008) achieved through a qualitative text analysis of internet discussions on pregnancy health and PPGP. As with the above studies, they adopted a thematic analysis approach which allows for easy comparison to themes produced. The authors acknowledged that the setting in which this information was gathered and how the information produced may have been influenced, not by the researcher, but by the bloggers themselves, potentially shaping discussion to increase focus on uncertainty and danger. Despite this insight, there is no mention of how the researchers themselves may be influenced by their own warranted beliefs (discussed further in Chapter 4) and how this could have impacted on data extraction through to analysis. Data which pointed to a lack of acknowledgement by health professionals in Fredriksen, Moland and Sunby (2008) was deemed a strong enough trait to be considered a category by itself, and perhaps helps explain why there has been a lack of information provided to pregnant women surrounding PPGP.

A lack of information provision is a strong theme throughout the qualitative literature on PPGP, and thus advocates further investigation in a UK population. Mogren, Winkvist and Dahlgren (2010) discovered that information on PPGP was not always forthcoming, as midwives felt time pressures prevented them from giving all women information on PPGP, despite acknowledging it was needed. The pregnant women in Elden, Lundgren and Robertson (2014a) said 'that they felt a brochure would have been useful.' with one woman stating that it would have been helpful to have '....at least known she wasn't alone in experiencing PGP.'

As a result, Elden, Lundgren and Robertson (2014a) suggested that women should be provided with information about the types of sensations that they are likely to experience to reduce fear. Persson *et al.* (2013) point to lack of knowledge as informants 'had not known much about PGP' (Persson *et al.* 2013), and Fredriksen, Moland and Sunby (2008) suggested the provision of information from health care professionals could help with coping and anxiety associated with PPGP. As with Mogren, Winkvist and Dahlgren (2010), Wellock and Crichton (2007), and Elden, Lundgren and Robertson (2014a), the desire for information around PPGP was evident in the study by Fredriksen, Moland and Sunby (2008); supporting the view that health professionals are not providing enough information to women in a timely fashion.

Fredriksen, Moland and Sunby (2008) stated that the over-arching theme, presented in their discussion, was that the pregnant women should take care of themselves, and that 'the full responsibility for future health and well-being is placed on the woman herself.' One question the authors raised is whether women push themselves too hard in order to maintain equality, as being pregnant is seen as a normal condition. They also suggested

that the awareness of PPGP potentially turning severe, and bloggers who reported having severe symptoms, may work towards intensifying feelings of fear and uncertainty and suggest that these reports may be out of proportion with experiences in the general population. The authors also discovered that the advice given by other sufferers was in the form of trying to reduce fear and worries, though some emphasised the worst case scenarios. As with the biopsychosocial symptoms of PPGP, the importance of health professionals and, in particular, information provision, is important to explore within a UK based population of PPGP sufferers, and is investigated in Chapter 6.

## **2.4 Potential causes of PPGP**

Despite causes of PPGP not being investigated within this thesis, it is still important to provide an insight into current theories about what may influence PPGP. Verstraete, Vanderstraeten and Parewick (2013) suggested that, after conducting a review of articles on the causes of PPGP, the most plausible explanation is it is a combination of hormonal and stability issues. In addition, Noren *et al.* (2002) put forward that altered muscle activation, primarily due to fear of pain, could be the cause of PPGP, with reduced and/or higher than expected activity of some muscle groups during movement when compared to non-pregnant women.

Damen *et al.* (2001) investigated 163 pregnant women, 73 who had developed PPGP during pregnancy and 90 who had mild or no PPGP without having previously had PGP. The inclusion criteria were not well documented, but it would appear that reporting pain around the pelvis was considered as PPGP. Those who had had PPGP in previous pregnancies, and those who developed it earlier in their pregnancy, were more likely to report PPGP as moderate to severe ( $p < 0.05$ ). There was no significant difference noted in employment status or their level of sporting activity during their pregnancy, both of

which are demographic factors often measured in PPGP studies (discussed further in the feasibility study, Chapter 7). However the main focus of Damen *et al.* (2001) was to find if SIJ laxity was attributable to PPGP. They found no difference in overall SIJ laxity between the PPGP group and the no PPGP group, though fail to show figures beyond a bar chart. They did, however, report that asymmetrical SIJ laxity was 37% in the PPGP group compared to 4.4% in the non-PPGP group, suggesting that asymmetrical SIJ laxity could be an influencing factor in PPGP. They noted that women who were nulliparous were more likely to be in the no PPGP group (48.9% of women in this group,  $p < 0.05$  compared to the PPGP group).

Hormonal changes have been put forward as a possible cause of PPGP for a number of years, yet this is supported by only small, low quality research (Verstraete, Vanderstraeten and Parewick, 2013). Although studies such as Nielsen (2010) have found increased pain in postpartum PPGP (ppPPGP) at times of menstruation, there is little support for the notion that hormonal changes during pregnancy impact upon PPGP. In Wu *et al.*'s (2004) review, it was suggested that the long-term use of oral contraceptives prior to pregnancy, which is believed to impact upon nociception, did not have an impact on ppPPGP. Bjelland *et al.* (2013), in their questionnaire based study of 91,721 women, used only location of pain as perceived by the patient as the sole method of identifying someone with PPGP, and looked at whether the contraceptive pill could be a factor in PPGP. The combined oral contraceptive pill had no association with PPGP up to 30 weeks gestation, though there was an observed increased risk of PPGP with those who used a progestin intrauterine device in the final year pre-pregnancy. The oral contraceptive pill was also found not to correlate with PPGP in the Björklund and Bergström (2000) study involving multinational participants, as well as in Damen *et al.* (2001) and Rost *et al.* (2006) studies, who also found no correlation between contraception use and

ppPPGP. Despite the lack of evidence to support contraceptive pill causing PPGP, it is still often measured in effectiveness studies and is, therefore, measured as demographic data for the feasibility study in Chapter 7.

Schauberger *et al.* (1996) investigated peripheral joint laxity during pregnancy in comparison to serum relaxin levels. Their findings, from 21 pregnant women followed from pre to post pregnancy, were that the knee and elbow joints became more lax during pregnancy ( $p < 0.001$ ). They also found that relaxin levels rise in the first trimester and remain elevated throughout the pregnancy. However, they concluded that joint laxity does not correlate to relaxin levels, though their lack of reporting clarity means that it is impossible to say why they arrive at their conclusions. Additionally, Albert *et al.* (1997) conducted a trial observing relaxin levels to determine whether there was an association with PPGP. A total of 2269 women were included, with 535 of those suffering with PPGP, as diagnosed through patient self-reporting and clinical examination using objective tests. Serum samples of 445 women were taken from each group, with the authors concluding there was no statistically significant difference in serum levels between the two groups at week 33 gestation ( $p > 0.05$ ). Although this appears to be a comprehensive observation of serum levels in relation to PPGP, it only takes a snapshot at week 33 and they failed to publish their results for scrutiny.

Despite Verstraete, Vanderstraeten and Parewijck's (2013) findings in their review that the evidence for hormonal changes is poor, they still put forward that hormonal changes are a reason for why PPGP exists. O'Sullivan and Beale (2007) argued that rather than hormonal changes directly impacting upon tissue integrity, the changes that do occur can lead to lowering of the pain threshold and changes to the inflammatory process. This is yet to be demonstrated in a clinical trial and at present remains hypothetical in relation to

the cause of PPGP. Therefore, it is suggested that there could be a relationship between how quickly relaxin levels rise (as demonstrated by Schauburger *et al.* 1996), or a relationship with how long serum relaxin levels have been raised, though this has not been tested in the published literature.

## **2.5 Epidemiology of PPGP: Incidence and prevalence**

Establishing an accurate incidence rate for any musculoskeletal issue remains a challenge for researchers (Cote *et al.* 2004). This is because true incidence can be affected by reporting rates by sufferers, quality of reporting accuracy by clinicians and researchers, and as outlined earlier, the diverse nature in which ailments such as PPGP are defined and ultimately diagnosed. Even when these data seem readily available, the discussion surrounding whether this accurately reflects those who need health care intervention or how much it may impact upon an individual means incidence rates alone do not tell the whole story (Cote *et al.* 2004). For example, research that has been conducted in one country may yield a different figure to that from another, something which is apparent within the PPGP epidemiology literature. However, despite the assumptions that are associated with incidence rates, reporting of prevalence of a condition such as PPGP does provide a broad sense of the seriousness of the problem, and a very rough estimation of how it could impact upon health services. From a research centric viewpoint, it can also help researchers establish a realistic timeframe and numbers likely to recruit to a study, both of which are essential in order to create an ethical approach to method planning and execution of an experiment.

A review by Kanakaris, Roberts and Giannoudis (2011) put forward that of the trials that most closely fit the Vleeming *et al.* (2008) definition of PPGP, the incidence of PPGP is between 16-25% of pregnant women. However, a longitudinal study based in Norway

explored the proportion of women who take sick leave whilst pregnant and the reasons for doing so (Dørheim, Bjorvatn and Eberhard-Gran, 2013). Using questionnaires to explore the reasons for absence from work, 2,918 women were involved in the study which found 75% had taken sick leave at some point during their pregnancy. Participants took an average of eight weeks sick leave, ranging from one to 40 weeks, the majority needing between four to 16 weeks (Dørheim, Bjorvatn and Eberhard-Gran, 2013). The authors suggested that PPGP was the reason for sick leave in 31.8% of cases, though the women were not subjected to objective testing to see if they had PPGP. Similarly, Ramachandra *et al.* (2015) performed a survey with 261 pregnant women in India who attended antenatal physiotherapy classes, and found that 37% of the women experienced PPGP.

A study by Bjorkland and Bergstrom (2000) investigated the claim that PPGP was largely sociocultural. By including pregnant women from Sweden, Finland, Zanzibar and Tanzania, they primarily used interviews as their basis for reporting of PPGP and LBPP in the 752 women recruited, with the women in Finland and Sweden additionally having a clinical examination to confirm no other internal organ involvement. They found incidence rates of 49% in Sweden, 77% in Finland, 66% in Tanzania and 81% in Zanzibar. As with Dørheim, Bjorvatn and Eberhard-Gran (2013), the data from Tanzania and Zanzibar cannot rule out other causes of pain in the lumbopelvic region because they failed to utilise clinical tests. Björkland and Bergström (2000) also noted that all four groups of women reported lumbopelvic pain onset, on average, in the third trimester. The Swedish group did, however, overlap into the second trimester, and the Finnish group's standard deviation suggests some women also reported PPGP in the second trimester. None of the Tanzanian or Zanzibar women reported earlier than third trimester. As there appears to be a range in PPGP onset, the trimester PPGP began in is measured in Chapter 6 and

7. Although Björkland and Bergström (2000) went some way to dismiss the notion of a purely socioeconomically driven pathology for PPGP, it did provide evidence of a large discrepancy between the different countries, suggesting there are factors other than mechanic-hormonal changes in pregnancy that influence its prevalence.

In a similar retrospective designed study based in the UK, Brown and Johnston (2013) surveyed women post pregnancy to ask if and when they had pain. If women rated their pain as a 7 out of 10 or higher on a VAS, it was considered significant and, therefore, reported upon. They found that 10% of women suffered with pelvic pain in trimester one, 29% in trimester two and 53% in trimester three. As with the studies above, the authors did not attempt to find what the cause of the pelvic pain was, and it was seemingly left to the participant to decide whether their pain was in the pelvic area. Unlike the aforementioned studies, the researchers used an approach of only considering PPGP if reported as 7 out of 10 or above. This is at odds with all other epidemiological studies looking at PPGP, and not only raises questions surrounding researcher bias (as they seem to be selecting only individuals who they deemed to be sufferers), but also the researcher's understanding of how PPGP impacts upon women. Additionally, asking participants to retrospectively report on PPGP leaves interpretation open to recall bias. The weaknesses of this study, combined with the range of incidence rates when investigated in different countries, advocates research in the UK to explore how PPGP behaves, and whether it responds to treatment. By conducting the studies in Chapters 6 and 7, it is considered that comparisons between a UK population and those above can start to be made.

Another problem with interpreting incidence rates for PPGP is that many studies have looked to encapsulate both LBPp and PPGP as one, meaning the prevalence for PPGP



alone from their results is not possible. It is, however, important to include research that has used these inclusion criteria, as it helps to form a picture of the potential impact of PPGP. Bastiaanssen *et al.* (2005) used an observational prospective cohort study and found that in 7,526 women in South East Netherlands, 84% developed pain around the lumbo pelvic region. Similarly, Mogren and Pohjanen (2005) used retrospective data collection from 891 pregnant women from Northern Sweden, and demonstrated that 72% developed lumbopelvic pain. However, in contrast, an earlier study by Endresen (1995) found that in their survey of 5,400 Norwegian women, 49% developed lumbopelvic pain.

Despite European guidelines by Vleeming *et al.* (2008) providing a short discussion around the epidemiology of PPGP, they failed to expand upon the large discrepancy in incidence rate reporting from different authors. However, one of the co-authors of the European guidelines for PPGP, H.B. Albert, found in an earlier prospective study that out of 1,460 Danish women, just over 20% developed PPGP (Albert, Godskesen and Westergaard, 2002). This research is likely to be the most reliable for measuring PPGP incidence rates (Pennick and Liddle, 2013) due to the paper being prospective, having a definitive diagnostic procedure, and allowing for consideration of PPGP separate to LBPp. However, because of the wide range in figures produced from different authors (as summarised in Table 2), it may not solely be due to diagnostic factors such as differentiation between LBPp and PPGP, with socio-economic factors suggested by Fredriksen, Moland and Sunby (2008) influencing prevalence due to the sick leave pay rules surrounding PPGP (Fredriksen, Moland and Sunby, 2008). Additionally, LBPp sick leave was recorded as up to 30% of pregnant women in two studies (Sneag & Bendo, 2007; Östgaard *et al.* 1994). Therefore, it could be that PPGP is disproportionality reported upon in countries where there is a financial motivation, and taking results from any of

these studies to apply to the UK population should be treated with caution. It was, therefore, considered important to explore financial impacts of PPGP within the qualitative study displayed in Chapter 6.

**Table 2: Incident rates of PPGP**

<b>Country</b>	<b>Incidence rate percentage (%)</b>	<b>Just PPGP</b>	<b>Authors</b>
<b>Netherlands</b>	84	No	Bastiaanssen <i>et al.</i> (2005)
<b>Zanzibar</b>	81	No	Bjorkland and Bergstrom (2000)
<b>Finland</b>	77	No	Bjorkland and Bergstrom (2000)
<b>Northern Sweden</b>	72	No	Mogren and Pohjanen (2005)
<b>Tanzania</b>	66	No	Bjorkland and Bergström (2000)
<b>UK</b>	10-53	Unclear	Brown and Johnston (2013)
<b>Norway</b>	49	No	Endresen (1995)
<b>Sweden</b>	49	No	Bjorkland and Bergstrom (2000)
<b>India</b>	37	Yes	Ramachandra <i>et al.</i> (2015)
<b>Norway</b>	32	Yes	Dørheim <i>et al.</i> (2013)
<b>Denmark</b>	20	Yes	Albert, Godskesen and Westergaard (2002)

In summary, the incidence rate of PPGP is unknown, particularly for UK women. There is a wide range of incidence rates reported, which could be due to a number of reasons,

such as research methods adopted and potential sociocultural and socioeconomic differences that exist. In order to obtain an incidence rate that could be applied to UK women to provide rationale for this thesis, a wide range of resources were consulted.

The Pelvic Obstetrics and Gynaecological Physiotherapy (POGP) group opt for prevalence between 50-70%, based heavily upon data combining low back and pelvic pain (ACPWH, 2011). There have been no NICE guidelines published, and very little has been issued from other professional organisations surrounding the incidence rates and management of PPGP, therefore POGP's suggestion seems to be the most accessible in the UK public domain. However, according to the Office for National Statistics (ONS), there were 690,820 maternities in the year 2013 in England and Wales (ONS, 2014), with an average maternal age of 30 years old. Applying the Alfred *et al.* (2002) prevalence rate of PPGP sufferers of approximately 20%, it would mean that would equate to just over 138,000 women every year suffering with PPGP. It is, therefore, essential that an epidemiological study be conducted to find a more accurate figure for PPGP incidence, though this is beyond the scope of this PhD. However, as there are potentially 138,000 sufferers, the study of an intervention such as KHA should be feasible, as there should be enough participants to make a study viable. Although, without first adopting a feasibility study in the UK, it is unclear whether a large-scale study investigating KHA could be conducted.

## **2.6 Post-partum pain**

Post-partum PPGP (ppPPGP) is a continuation of PPGP beyond pregnancy and appears to be a significant problem, albeit on a smaller scale. Vleeming *et al.* (2008) put forward that around 7% of women suffer with ppPPGP at three months post-partum. A similar figure was found in Albert, Godkesen and Westergaard (2001), who investigated

the prognostic scenario with ppPPGP, 24 months post-partum in Danish women. Of the 405 women in the PPGP group, 8.5% still suffered daily pain, though on subgroup analysis, those who had pain emanating from the pubic symphysis were found to have no pain at six month follow up. This suggests that there are specific sub categories of pelvic pain that have different impacts upon chronicity. However, as with the epidemiology studies, there exists an inconsistency of results for ppPPGP.

Norén *et al.* (2002) found at three years follow up that 20% of women who had had back or posterior pelvic pain during pregnancy still had pain. This is supported by a more recent study by Bergstrom, Persson and Mogren (2014) who conducted a 12 month follow up trial to assess the impact that PPGP had upon women post pregnancy. They found that approximately 20% of women who had developed PPGP during their pregnancy, at 12 months follow up were still suffering with continuous or recurrent pain. Rost *et al.* (2006) investigated the long-term impacts of ppPPGP, focusing upon pain levels and functional tasks. They surveyed 430 women, who were considered to have PPGP if they self-reported it, not through clinical objective measures. They found that 90% of women, who experienced PPGP and received treatment for it during pregnancy, reported a good recovery post-partum (Rost *et al.* 2006). This suggests that treatment for PPGP whilst pregnant has a protective effect from producing chronicity to ppPPGP, if the numbers affected are compared against Noren *et al.* (2002) and Bergstrom, Persson and Mogren's (2014) findings.

However, as the numbers post-partum are very similar to that of PPGP sufferers in Albert, Godkesen and Westergaard (2001), it may help to explain the discrepancy, as an uncontrolled for variable of treatment for PPGP may have produced lower figures for Albert, Godkesen and Westergaard (2001) and higher figures for Noren *et al.* (2002) and

Bergstrom, Persson and Mogren (2014). This advocates the further investigation of interventions for PPGP, such as KHA, and provides support from the study outlined in Chapter 7.

Rost *et al.* (2006) found that those who did not have ppPPGP had been slightly more likely to have had an instrumental delivery, whereas those who had ppPPGP were more likely to have a protracted labour time and more likely to report an extremely painful delivery. A study by Bjelland *et al.* (2011), on investigating 74,973 women, found that PPGP was more likely in women who had had early menarche (20% of PPGP population) compared to those who had menarche after the age of 14 (12.7% of the PPGP population). Women were also more likely to have PPGP if they had high Body Mass Index (BMI), low maternal age, previous delivery or low back pain and if their education level was deemed low or that they had a physically demanding job (Bjelland *et al.* 2011).

Albert, Godkesen and Westergaard (2001) found that, in their study of 405 women with PPGP, the possible factors that could increase the chance of a woman to continue to have pelvic pain for two years post pregnancy were: an increase in age, unskilled work, a high intensity of pain, poor mobility and not formally educated. In a longitudinal study by Bjelland *et al.* (2012), a questionnaire method was conducted to survey 41,421 pregnant women; they found that of those who reported PPGP at 30 weeks gestation, 78% had recovered by 6 months post-partum, with 3.5% reporting significant complaints. The figure of 22% still affected at 6 months by ppPPGP is in line with Noren *et al.* (2002) and Bergstrom, Persson and Mogren (2014). Those women who reported emotional distress during pregnancy were at an increased risk of reporting PPGP after delivery. The authors suggest that the increase in emotional distress could have been the cause of the maintenance of PPGP post-partum (Bjelland *et al.* 2012). The authors did acknowledge,

however, that although a questionnaire is an accepted method to gain information on a large group, a clinical interview is the best way to determine emotional distress (Bjelland *et al.* 2012). The authors concluded that if emotional distress could be controlled during pregnancy, then postpartum persistence of PPGP may be reduced. This, therefore, supports the investigation of how PPGP impacts upon sufferers in the UK, outlined in Chapter 6, whilst considering whether an intervention such as KHA can impact upon general wellbeing, outlined in Chapter 7.

A study by Engeset, Stuge and Fegran (2014) explored how ppPPGP affected Norwegian women, utilising a phenomenological-hermeneutical approach to semi-structured interviews with five ppPPGP sufferers. The authors gave a broad outline of how they eventually arrived at their three main themes, but they failed to go into detail about the data reduction phase, which lead to the themes put forward. Trustworthiness was attempted to be strengthened by using a physiotherapist with extensive experience in the field, but who was removed from the individual's experience, and their interpretation of the data was performed in collaboration with the third author. Although attempting to provide some objectivity to the findings, it portrays to the reader that reflexivity had not been given enough consideration on how warranted beliefs impact upon the data analysis. They acknowledged that they could not be certain that data saturation had been met, though felt that new data did not bring about new information. The informants declined the opportunity to read the transcripts and findings; known as member checking, this is one way of attempting to validate the findings. If conducted, it is considered a method strength. When member checking is not used, the interpretation by the data analyser may have misjudged emphasis on what was said.

The themes created by Engeset, Stuge and Fegran (2014) are descriptive in nature, though within the discussion the authors did expand upon their findings. 'Activity and pain' theme encapsulated the physical suffering the women go through, with changes to ADL's and the desire to increase physical activity indicated by the authors as being prominent in the raw data. This is not surprising given the studies discussing impacts to ADL's earlier within this chapter. In further confirmation of the research put forward earlier in this chapter, information and knowledge was considered of high importance to the PPGP sufferers, with coping and 'support from family, friends and health professionals ... essential' (Engeset, Stuge and Fegran, 2014). This suggests that ppPPGP and PPGP are similar, providing some validation for investigation of both to inform one another, and perhaps indicating treatments found to be effective in a ppPPGP group could be transferred to ante natal PPGP.

However, Engeset, Stuge and Fegran (2014) found an emphasis on other topics. Under 'lack of acknowledgment of pain and disability', the researchers indicated there was psychological stress caused as a result of frustration at not being able to do physical activities as they had pre pregnancy. They interweaved their findings with their discussion on how pain can impact on the emotional and mental health of an individual, and put forward their views as to why they felt women experienced such psychological stress. The lack of emphasis on psychological outcome measures used by quantitative researchers suggests that these symptoms of PPGP are frequently overlooked. This, coupled with only five interviews taking place, indicates a warrant for further investigation as to whether psychological symptoms impact upon PPGP sufferers in the UK, and is therefore explored in Chapter 6.

Further findings from Engeset, Stuge and Fegran (2014) point to the broader impacts of PPGP. A lack of understanding from colleagues and employers, partners roles at home changing, and women feeling they were more dependent on their partner were all discussed briefly and support the findings presented earlier from Elden, Lundgren and Robertson (2013). It would therefore be worthwhile to determine whether this relationship impacts on the wider social unit who are closely involved with the PPGP sufferer, extended to women in the UK, and is again explored in Chapter 6.

## **2.7 Chapter summary**

Pregnancy related pelvic girdle pain is considered an outright entity, and in combination with its high prevalence rates and risk of developing into a chronic condition, should be investigated further within the UK. Although there has been a growing body of qualitative literature to extend knowledge of how PPGP affects the pregnant woman, further high quality work is needed, with views of pregnant women from the UK currently lacking. Chapter 6 aimed to address this gap in the literature, and puts forward similarities and unique insights into PPGP from semi-structured interviews with stakeholders. This chapter has also served to highlight that it is also necessary to investigate treatments which may have a positive impact upon PPGP symptoms, as not only do sufferers discuss pain, dysfunction and changes to QoL, but there is a potential for the condition to become chronic in the form of ppPPGP. Therefore, Chapter 7 aimed to investigate the feasibility of research into KHA effects on PPGP, primarily using outcomes for pain and ADL. Although findings of Chapter 6 help to support the study in Chapter 7 through the confirmation that women are indeed looking for treatment for their symptoms, the existing literature on PPGP management discussed in the following chapter provides a strong rationale for investigation of KHA for PPGP.



## **Chapter 3**

### **Management and Interventional approaches for Pregnancy related Pelvic Girdle Pain**

A literature search pertaining to the management of pregnancy related pelvic girdle pain was conducted via databases AMED, CINHALL, EMBASE, MEDLINE and PubMed. Search terms included: "Pregnancy related Pelvic Girdle Pain", "Pregnancy related low back pain", "Pelvic Pain", "Pregnan\* AND pain", "Symphysis Pubis", "Symphysis Pubis Syndrome". All of the above were also searched using AND "acup\*", "treatment", "management", "intervention", "pain relief", "exercise", "physio\*", "physical therap\*", "exercise", "pelvic belt", "medication", "analgesic\*", "drugs". MESH headings were used when available. Reference lists of relevant publications were also searched. Only publications that were written in English were included, with title and abstract reading performed to ascertain the appropriateness of the study for this chapter.

#### **3.1 Background**

Several literature reviews (Kanakaris, Roberts & Giannoudis, 2011; Vermani, Mittal & Weeks, 2010; Pennick & Young 2013) have highlighted the need for better quality research into the treatment of PPGP, and are supported by the European guidelines on diagnosis and treatment of PGP (Vleeming *et al.* 2008). In a literature review and proposal for a clinical care pathway for PPGP, Verstraete, Vanderstraeten and Parewijck (2013) stated that PPGP has a unique clinical presentation and as such should have specific management. Pritham and McKay (2014) stated that research in pregnancy is not as common as it should be, and highlighted the detriment to pregnant women's mental health if pain is left untreated. Baylis (2010) stated that by not investigating pregnant

women through research, it denies the possibility of new therapies that could be of benefit and, as a result, a culture of under treating during pregnancy prevails. Pham (2014) believed this is as a result of serious adverse events in drug trials in pregnancy, creating a culture of hyper vigilance.

### **3.2 Medication use**

Hollyer *et al.* (2002) attributed the apprehension to including pregnant women in research, at least in part, to poorly researched side effects of drugs, such as the thalidomide cases of the 1950's and 1960's, which had had little investigation into its potential harm before being released for morning sickness. As a result, pharmacovigilance has prevailed, whereby review panels look at effects and adverse events in equal detail, and extends to medical practitioners who seem reluctant to prescribe medication to pregnant women (Pham, 2014). However Pham (2014) indicated that many medications prescribed to pregnant women have not been tested in clinical trials for safety. Although not the only reason, a lack of confidence in medication has likely contributed to practitioners seeking alternative treatments to help control symptoms of pain (Hollyer *et al.* 2002). Vermani, Mittal and Weeks (2010) concluded in their review that non-steroidal anti-inflammatory drugs (NSAIDs) were safe and had some effect on pain, however, many commonly used NSAIDs are considered to carry an extremely large risk to the foetus if ingested in the first trimester, or after 30 weeks gestation (Pritham and McKay, 2014). Not surprisingly, this corresponds with a general vigilance on pregnant women taking medication. To try and gain an appreciation of the medication consumption during pregnancy, Nordeng, Koren and Einarson (2010) used a structured Internet based questionnaire to investigate the views of pregnant women on medication specifically during pregnancy. They surveyed 866 pregnant women, which equates to approximately 15% of the

pregnant population of Norway (Nordeng, Koren and Einarson, 2010). Caution with taking medication appeared prominent in 87% of women, and 61% felt it better for the foetus if they abstained from taking medication. The authors put forward that during pregnancy, women were very cautious and unsure of taking medication. However, they also found that most women (78.6%) reported that they had used medication during pregnancy, most commonly paracetamol, presumably for pain relief (Nordeng, Koren and Einarson, 2010). In support of these findings, Kennedy (2011) found that 85% of Australian pregnant women take some sort of medication, with analgesics the most commonly ingested. Regardless of whether the general negative mentality towards medication is justified or not, it is appropriate to investigate what other avenues pregnant women, and health practitioners, can seek to help ease pain such as PPGP.

### **3.3 Physiotherapy in PPGP**

Numerous treatments are advocated for the treatment of PPGP. The pelvic girdle belt was proposed by Mens *et al.* (2006) to simulate the contraction of stabiliser muscles that usually act upon the lumbopelvic region. The researchers found that when a pelvic girdle belt was applied to 25 women with PPGP, joint laxity in the SIJ was reduced statistically significantly ( $p < 0.001$ ). They also found that when the belt was administered, the ASLR pain score also reduced ( $p = 0.005$ ). However, this study was conducted on post-partum women and so it remains speculative as to whether it would have a similar effect during pregnancy. More generally speaking, their results only apply to short term findings and do not look at outcome measures outside of immediate application. No ADL outcome measures, or attempts to look at medium term effects, were attempted to be investigated, which means the study has little clinical relevance other than to say that a pelvic belt helped to ease pain on a ASLR. In addition, Vleeming *et al.* (2008) and Pennick and Liddle (2013) found that, on review of the literature, there is only low quality evidence to

support the pelvic girdle belt for reduction of PPGP. That said, it is still considered as part of standard practice, as is part of the standard physiotherapy control outlined in the feasibility study in Chapter 7.

Vleeming *et al.* (2008) found evidence for a modified back class to be of moderate to low methodological quality, and the two studies reviewed found no significant difference in pain. Vermani, Mittal and Weeks (2010) and Eggen *et al.* (2012) support this view, as preventative exercises and education to prevent symptoms occurring seem to have little impact. This is reiterated by Stafne *et al.* (2012), who looked at standard back classes for 761 pregnant women suffering with lumbopelvic pain over a 12 week period. They compared it to a non-exercise group, finding no significant difference between the two. However, George *et al.* (2013) investigated whether a multimodal approach to lumbopelvic pain in pregnancy, including manual therapy, stabilisation exercises and patient education, was superior to standard care, which included general aerobic exercise, pain medication and heat. They found that, in 169 participants, those who attended the multimodal session of up to six sessions were, on average, lower in pain scores and functional disability, as assessed by the Numerical Rating Scale (NRS) and Quebec Disability Questionnaire, at the final assessed point ( $p=0.01$ ). This indicated a multimodal approach may be of some benefit to a PPGP sufferer, and is thus included in the feasibility study in Chapter 7 as part of the control intervention.

Despite these studies indicating some beneficial effects of exercise on PPGP, its uptake is dependent on its acceptability. Downs and Hausenblas (2004) used an open-ended questionnaire to examine 74 postpartum women's beliefs of exercise whilst pregnant. The most salient behavioral advantages reported were improving mood, stamina and more likely to aid weight control. Interestingly, most respondents found their fiancé or

husband to be of most influence on performing exercise. The most common barrier to people exercising during pregnancy were physical limitations, and so the authors suggested that healthcare professionals aim to reduce these barriers (Downs and Hausenblas, 2004). Clarke and Gross (2004) found similar results, with women decreasing their physical activity during pregnancy. One of the suggestions for this, from semi-structured interviews of 14 women in the UK, was that physical exertion posed an inherent risk to health, and that a third of respondents had stopped doing exercise because of potential danger associated with pre-pregnancy activity (Clarke and Gross, 2004). In a more recent study, Evenson and Bradley (2010) found that pregnant women felt there were several benefits of light exercise; 73% agreed moderate exercise to be beneficial, but only 13% agreed that vigorous exercise was acceptable. The work put forward by Evenson and Bradley (2010) suggested similar apprehensions as is found in medication use, suggesting that although the majority of women considered exercise to be acceptable, there was still concern over the potential adverse events associated with exercise during pregnancy.

Despite the issues raised above, Vleeming *et al.* (2008) recommended the use of an individualised exercise programme, to include advice on ADL's and maladaptive movement patterns, and the use of individualised physical therapy. They also recommended information provision as part of any treatment regime, though this has not been found to be an effective standalone treatment (Vermani, Mittal and Weeks, 2010; Gutke *et al.* 2015), but has been suggested by Elden, Lundgren and Robertson (2014a) as something which PPGP sufferers value. Vleeming *et al.* (2008) did not state why exercise and advice should be included, considering the poor evidence base to date, yet it is likely due to the fact that there are very few other options available. However, one such option is acupuncture, which has a growing evidence base for PPGP.

### **3.4 The use of acupuncture in PPGP**

For over 2000 years, acupuncture has been administered as a treatment, with its origins likely from ancient China (Hopwood, 2004). Although acupuncture can adopt many forms, it is often defined as “piercing of the skin with a fine needle” (Roschke *et al.*, 2000, p.73). The Chinese philosophy of health is based upon the ideology of Yin and Yang, where two opposing forces constantly vie for supremacy, but when in harmony, will allow for good health (Hopwood, 2004). Pain will be a direct result of an imbalance of this delicate interplay, therefore in order to return to good health, the Yin and Yang balance must be restored. This theoretical approach is often referred to as Traditional Chinese Medicine (TCM) acupuncture, which consists of meridians, or energy pathways, that run over the whole body (Lu and Needham, 2002). Traditional Chinese Medicine theory states that acupuncture could help maintain this equilibrium, in which inserting needles into specific points around the body (acupoints) influence Qi, the energy life force associated with maintaining a Yin Yang balance (Deadman, Al-Khafaji, and Baker, 2001). Qi is believed to circulate in meridians, with each meridian containing a number of acupoints which have specific functions or effects to the body (Macioca, 1994). Thus by stimulating Qi within acupoints on meridians via acupuncture, any imbalance to Yin and Yang could be resolved, allowing the illness/pain to dissipate (Hopwood, 2004).

In practice, a TCM clinician would look for acupoints on meridians that are said to directly affect the ailment. In a condition such as PPGP, acupoints may be situated on the lower back and pelvis, but could also be found on the ankle or hand, and thus can be referred to as body acupuncture (Flaws and Sionneau, 2004). This is the most common form of acupuncture, however in recent decades, new forms of acupuncture have developed, known as micro systems (Hopwood, 2004), located on the ear, scalp, hand or foot (Lao, 1996).

These micro systems are contained to the area in which its name suggests (i.e. hand acupuncture consists of using acupoints only on the hand), but are said to affect the whole body (Hecker, Steveling and Peuker, 2006). Korean Hand Acupuncture is one such micro system, and has found favour with many acupuncturists worldwide (Kim *et al.* 2005). It works on the theory that each hand represents 14 'micro meridians' and therefore each body acupuncture point used in TCM can be found and represented as an acupoint on the hand (Yoo, 2001). It is practiced by needling acupoints found only on the hand and is the focus of the research conducted in Chapters 5 and 7, with rationale for this approach discussed later in this chapter.

Acupuncture theory has also been developed from a western medical perspective, more of which will be discussed in section 3.6. There has been a plethora of published research pertaining to acupuncture effects and effectiveness, with NICE guidelines for migraine (NICE, 2012) advocating its use. However it is not a universally accepted treatment, with a number of studies (Elden *et al.* 2008; Haake *et al.* 2007; Cherkin *et al.* 2009) indicating acupuncture groups producing effects no better than a sham group. This counterargument to acupuncture has such a presence in researcher commentaries, that the placebo literature surrounding acupuncture is discussed in depth later in this chapter. It has also driven the rationale for the study outlined in Chapter 5 and method of the study in Chapter 7, yet it does seem that acupuncture is considered an acceptable intervention by pregnant women.

Ternov *et al.* (2001) looked at the impact of acupuncture in LBPP and PPGP with late stage pregnancy in 167 consecutive case studies, using the outcome measure of midwife belief of effect, on a five point Likert type item. They found 72% reported the analge-

sic effect of acupuncture to be good or excellent. Their results should be treated with extreme caution, and perhaps considered to have little clinical relevance, in the face of patient reported outcomes being absent and the use of a valid and reliable outcome measure not being used. However, the findings do suggest some benefit towards acupuncture being used for LBPp and PPGP, and is comparable to other published studies such as Martensson, Kvist and Hermansson (2011), who stated that acupuncture was used for pelvic pain in over 18% of the midwife units who treated PPGP in Sweden. In contrast, a study by Beales *et al.* (2015), who investigated PPGP and LBPp management by physiotherapists in Norway and Australia, only 1.5-3.9% would consider using acupuncture. As the authors also asked participants to state what they would use in a non-pregnant PGP sufferer, it can be observed that 3.1-3.9% of physiotherapists would use acupuncture (Beales *et al.* 2015). This suggests that acupuncture in Norway and Australia are considered a lot less often than in Sweden, although the respondents were from a generic physiotherapy population rather than specific clinical interest groups as used by Bishop *et al.* (2015).

In a study investigating the management of LBPp, Bishop *et al.* (2015) found that physiotherapists based in the UK tended to treat women within the NHS in three to four sessions over a three to six week period, though around 14% treated women five times or more and 17% would treat a patient over a period of seven to 10 weeks. The 629 physiotherapists who responded to the postal questionnaire reported a range of treatments that they commonly administer, 94% prescribing home exercises and 24% suggesting they would consider acupuncture in the patient vignette given.



However, of those who were members of an acupuncture clinical interest group, 44% stated they would consider using acupuncture for the vignette provided. Further to this, 37% of those who responded suggested that they would use acupuncture for women with LBPp. Notably, the acupoints used were all TCM body acupoints, with 31% of practitioners considering the use of points within the hand as part of their treatment. In addition, the authors commented that there was considerable variation in treatment approaches. Although this study pointedly focuses upon LBPp and PPGP, as outlined in Chapter 2, there is overlap between the two conditions, both in terms of treatment approach and research inclusion. Specifically to the rationale for this thesis, the consideration of using points on the hand by 31% indicates some rationale for using KHA, whilst the method of six sessions over an eight week period within the feasibility study in Chapter 7 reflects practice in some areas of the UK as found by Bishop *et al.* (2015).

Further support for acupuncture was observed in Wang *et al.* (2005), who conducted a survey of patients and practitioners on the use of Complementary and Alternative Medicine (CAM), of which acupuncture is considered a part of. They found that out of the 104 clinicians surveyed, 61% considered CAM for their patients. In addition, they found that 61% of 950 pregnant women with LBPp would consider using CAM for their treatment. In support of these findings, Elden *et al.* (2005) found that pregnant women were most satisfied when being in the intervention of true acupuncture or stabilising exercise group, when compared to standard care. Soliday and Hapke (2013) also discovered, in their survey of 137 pregnant women, that the use of acupuncture for pregnancy related issues was considered beneficial. However, not all researchers have found acupuncture to be wholly acceptable.

Waterfield *et al.* (2015) conducted three focus groups and three individual interviews with 21 UK based physiotherapists exploring the role of acupuncture in LBPp. They adopted a thematic approach to data analysis by coding and categorising data to develop themes, and presented a clear audit trail to help inform the reader as to how they arrived at their conclusions, including raw data for each category and theme to support their interpretation. They provided a clear philosophical underpinning which helps to strengthen the rigour of the study, as it is clear what may have influenced the data display when analysing the data. Their findings demonstrated that physiotherapists are reluctant to perform acupuncture in pregnant women, primarily due to fear of causing an adverse event. This is in contrast to the aforementioned studies, suggesting a difference in opinion within healthcare practitioners as to the safety of acupuncture during pregnancy. It is, therefore, relevant to consider the safety literature to understand if this reluctance is justified.

### **3.5 Safety of acupuncture in pregnancy**

The importance of establishing the best evidence on the types, severity and occurrence of adverse events as a result of receiving acupuncture during pregnancy is central to shared decision making and informed consent (Clarkson, O'Mahony and Jones, 2015). The MRC framework, discussed in Chapter 4, details the need for producing treatments that are acceptable to an individual, with adverse events being a potential impacting factor. A systematic review by Park *et al.* (2014) looked to establish the safety aspects of acupuncture during pregnancy, concluding that there are few adverse events associated with acupuncture when applied correctly. However, on critique of this systematic review, the definition of acupuncture was unclear, and no comparison was made between adverse events in acupuncture and non-acupuncture groups (Clarkson, O'Mahony and

Jones, 2015). This meant that it was difficult to ascertain whether penetrating acupuncture had more or less safety issues when compared to non-penetrating interventions. In order to meet the objectives of the feasibility study in Chapter 7, accurate adverse event reporting is crucial to establish, and in order to do this, recommendations put forward by Clarkson, O'Mahony and Jones (2015) were adopted.

Adverse event reporting has been poor throughout all research topics, and prompted an international committee to release the CONSORT statement on reporting of harms (Ioannidis *et al.*, 2004). It put forward recommendations on the detail needed to accurately report adverse events, and it was used to help guide the data extraction for the systematic review conducted by Clarkson, O'Mahony and Jones (2015). They compared penetrating acupuncture to non-penetrating interventions, which included 'placebo' acupuncture as well as general physiotherapy interventions (see appendix 12). Overall, it was found adverse event reporting to be poor on several counts. Out of the 25 studies identified as being eligible, 17 remained in the final analysis due to eight not mentioning adverse events at all. Of those studies that were included, only two provided adequate description to allow for accurate incidence rates to be calculated. It was also noted that some studies reported effects that would likely be perceived as beneficial, or at the very worst not perceived as negative, as adverse events. To address the quality of reporting, the authors suggested that researchers not only conform to CONSORT guidelines, but provide additional information to allow the reader a better understanding of the frequency of adverse events. The additional information suggested can be seen in the table presented in Appendix 2, and was adopted in the study outlined in Chapter 7 to ensure accurate reporting.

Finally, taking into account the poor quality of reporting, the trend for adverse event occurrence was very similar in the penetrating and non-penetrating groups, and the adverse events that did occur were largely minor and transient (Clarkson, O'Mahony and Jones, 2015). This lends credibility to investigating acupuncture in pregnancy, though due to small numbers within the systematic review, continued monitoring and reporting should be continued. In addition, decisions on treatment should not be made outside of the context of potential benefits, with several studies investigating acupuncture effectiveness for PPGP.

### **3.6 Acupuncture for PPGP**

In the UK, a PPGP sufferer is likely to be referred to a physiotherapist for treatment and management of their condition (ACPWH, 2011). According to the Association of Chartered Physiotherapists in Women's Health (ACPWH), treatments that physiotherapists are likely to perform as a result of pregnancy related issues are stabilising and strengthening exercises, and for pelvic pain, acupuncture (ACPWH, 2011). Vleeming *et al.* (2008) suggested acupuncture research to be of a higher quality than other treatment modalities associated with PPGP, yet despite this, further large scale, robust trials need to be conducted (Vleeming *et al.* 2008; Pennick and Young, 2013). Thus a feasibility study (as conducted in Chapter 7) is needed to ensure any subsequent larger scale research is valid (Craig *et al.* 2008). However, specific to PPGP, there are several studies that have researched acupuncture benefits using a variety of acupuncture approaches.

A two armed study by Lund *et al.* (2006) investigated 70 PPGP sufferers, randomising women to either superficial or deep acupuncture, with symptom changes measured through a VAS for pain over the last week, and the Nottingham Health Profile (NHP) for

health related quality of life. Those included had to meet the inclusion criteria of gestation between 22-36 weeks, had pain for at least two weeks, and were diagnosed with PPGP (as outlined in table 3). Superficial acupuncture involved needles being inserted subcutaneously, whereas the deep needling group had needles inserted to a range of deeper depths (depending on where the needle was inserted). Lund *et al.* (2006) reported they had 23 drop outs, meaning that only 47 women were included in analysis. All drop outs were accounted for with an explanation given for non-completion, none of which were related to acupuncture. Although they do not provide statistical values for between group comparisons, they state that there was no difference for morning or evening pain. However, they then amalgamated both groups to compare baseline and final pain scores for turning in bed, walking and sit to stand (all in the morning and evening), looking to analyse whether there was a statistically significant difference between the amount of people who reported improvements, the amount who reported no change and the amount who reported worsening of symptoms.

For turning in bed (morning  $p=0.03$ , evening  $p=0.04$ ), walking (morning  $p=0.004$ , evening  $p=0.001$ ) and sit to stand (morning  $p<0.001$ , evening  $p=0.03$ ), results showed more women reported reduction in pain than those who reported no change or those reported worsening of symptoms. Similarly, NHP scores were noted to have better emotional reactions ( $p=0.0007$ ). Although this study tentatively suggests acupuncture, regardless of insertion depth, may have some beneficial effects to pain and emotional state, it does not provide any insight into acupuncture effect when compared to a control, such as the studies discussed below.

Wedenberg, Moen and Norling (2000) investigated the impact of acupuncture on those with LBPp and PPGP in Sweden, asking women to complete an NRS for morning and

evening pain as well as a DRI for function. They were identified as having LBPp or PPGP through provocation tests, though the specifics were not expanded upon and Clarkson, O'Mahoney and Jones (2015) and Gutke *et al.* (2015) found the method of reporting poor overall when rated on the PEDro scale (4/10). There were two groups; the acupuncture group, who received ten sessions over a four week period, and a physiotherapy group, who received an individualised treatment programme of ten 50 minute sessions within an eight week period. They recruited 30 women to each group, with two drop outs in the acupuncture group and 12 in the physiotherapy group. Demographic data on age and gestation were also taken, which were shown to be homogenous across the groups. They found that the acupuncture group demonstrated improvements on NRS ( $p=0.01$  for both), and statistically significant improvements when compared to the physiotherapy group ( $p=0.02$  for morning pain,  $p=0.01$  for evening pain). For DRI, all disability items were found to be improved in the acupuncture group, with the physiotherapy group demonstrating worsening of symptoms in seven of the twelve items. However, there was no mention of credibility of the interventions, which could be a variable in itself, and is discussed later in this chapter. The authors expressed surprise at their results, as they expected only pain to be improved, not function, for the acupuncture group. This suggests that reduced function is a direct cause of pain intensity, lending support for the inclusion of the PGQ, an outcome measure for ADL's developed specifically for PPGP, in the study outlined in Chapter 7.

A similar study by Kvorning *et al.* (2004) also found an acupuncture group to produce better outcomes for pain ( $p=0.01$ ) and function ( $p=0.001$ ) when compared to a control group. They investigated the effect of acupuncture on LBPp and/or PPGP in 72 women over a two year period, randomised to either an acupuncture or control group (details of the control group were not provided, though it would appear to be standard care which

did not include physiotherapy). They had dropouts from the acupuncture group due to unpleasantness of the acupuncture, one lost to follow up and another not completing the outcomes correctly. They collected demographic information on pain, employment, age and gestation, and used a VAS for worst and best level of pain that week and a non validated three point Likert type item for eight ADL's. To the benefit of reliability in results, the authors took outcome measures on a weekly basis, not a before and after treatment approach as adopted by Wedenberg, Moen and Norling (2000).

However, Kvorning *et al.* (2004) fail to express whether the baseline characteristics were homogenous, leading to questions being raised around the reliability of the supposed independent variable, acupuncture, causing changes to outcomes. No credibility or belief around treatment effect was measured, which means this too could have been a potential impacting factor. Although this study should accompany caution when interpreting the results due to the risk of low reliability through poor reporting, the results do resonate closely to that of Wedenberg, Moen and Norling (2000) and other acupuncture studies outlined later in this chapter. Further to this, if the control group was just standard care that did not include physiotherapy, the finding of 49% of control participants having symptoms getting worse lends credibility to the view that PPGP progressively gets worse as time and pregnancy progresses. This indicates that a successful treatment may halt progression of symptoms, not necessarily improve symptoms, and will be discussed in Chapter 7.

Da Silva *et al.* (2004) also obtained very similar findings to that of Wedenberg, Moen and Norling (2000) and Kvorning *et al.* (2004). They investigated LBPp and PPGP, and administered acupuncture between 8 and 12 times over an eight week period. They com-

pared a group who received acupuncture plus medication to a group who had only access to usual pain relieving medication, in Brazil. Twenty seven women were in the acupuncture group and 34 in the control group. As with Wedenberg, Moen and Norling (2000), their primary outcome was an NRS, measuring pain at present, pain over the last 14 days and maximum pain in the last 14 days, and were taken at five different time points. They also asked participants to complete an NRS for general activities, working and walking, and took demographic data on age, gestation, height and weight. It was reported that there was no demographic difference between the groups, yet fail to provide any statistics to support the claim. They noted that the control group did not register pain improvements, and although they state the pain level fluctuated around the same level as at baseline, the graph they provide indicates a trend of gradually worsening pain over time, consistent with Kvorning *et al.* (2004).

In comparison to the control group, the acupuncture group reduced pain significantly in all three NRS pain measures ( $p < 0.01$  for all three), and again in the three functional NRS items ( $p < 0.01$ ). The author did not use a validated functional activity scale which would have strengthened their findings. No credibility or belief in intervention was assessed, and the amount of patient contact between the two groups was not controlled for, as the control group did not receive contact other than at the beginning and end of the data collection period. These factors, combined with the poorly reported homogeneity of groups at baseline, reduced the reliability of the study markedly, with Clarkson, O'Mahoney and Jones (2015) giving a PEDro score of 3 out of 10. Wedenberg, Moen and Norling (2000), Kvorning *et al.* (2004) and Da Silva *et al.* (2004) all found positive impacts upon PPGP when acupuncture was administered, and provides some rationale for using acupuncture within PPGP; however, all three studies are considered to be of poor quality and so further high quality studies need to be appraised.



A large three-armed RCT, comparing standard care (SC) (n=130), SC plus acupuncture (n=125) and SC plus stabilising exercises (n=131) for PPGP was conducted by Elden *et al.* (2005) over 27 maternity care centres in Sweden. They included women from the second and third trimester, with singleton foetus and diagnosed with PPGP. Objective measures conducted were the P4, FABER, Trendelenburg, lasegue and palpation of the pubic symphysis, which were also used as subsequent secondary outcome measures for PPGP severity post treatment. The SC comprised of detailed information surrounding PPGP management and a stabilising belt, with the acupuncture group attending for 12 sessions over a six-week period, and the stabilising exercise group attending for six hours of one to one exercise over a six-week period. The primary outcome, as in Kvorn- ing *et al.* (2004), was a VAS, for morning and evening pain. They had 61 drop outs in total, with 15 of those from the acupuncture group through loss to follow up, declined further intervention or had an early delivery. They took baseline demographics of age, gestation, work status and physical activity levels, and found the three groups to be homogenous on these factors.

Elden *et al.* (2005) found that the acupuncture group produced the most benefit for morning pain when compared to SC ( $p < 0.001$ ) but no difference between the acupuncture group and stabilising exercise group ( $p$  value not given). For evening pain acupuncture was superior when compared to SC ( $p < 0.001$ ) and stabilising exercises ( $p < 0.02$ ). For a secondary outcome measure of changes to objective assessment markers, it was difficult to ascertain what the comparisons were for each subgroup, but appeared to favour the acupuncture group in most instances. However, despite the strengths of this work, outcomes were measured only at baseline and at end of treatment. As with the aforementioned studies, there was no attempt to measure credibility or believability of the treatment provided, leaving it questionable as to whether this was a potential factor

in the results displayed. The quality of the study was considered high by Gutke *et al.* (2015), scoring 8/10 on PEDro, and when combined with positive results for acupuncture, explains why systematic reviews cautiously recommend acupuncture for PPGP (Pennick and Young, 2013; Gutke *et al.* 2015).

In the largest acupuncture-only for PPGP study to date, Elden *et al.* (2008), used several outcome measures in their RCT comparing a standard care plus penetrating acupuncture group with standard care plus non-penetrating acupuncture. A total of 115 women were randomised, with baseline demographics of maternal age, gestation, amount of exercise, week when PPGP began, employment type and affect PPGP has upon employment. In all but one of the demographics, there was no significant difference between the groups, with more women in the penetrating group still in regular work when compared to the non-penetrating group ( $p=0.041$ ) being the only heterogeneous variable assessed. The dropout rate was difficult to ascertain, though it would appear an approximate 7% drop out in both groups.

Elden *et al.* (2008) included assessment of credibility of the penetrating and non-penetrating interventions using a modified version of the Borkavec and Nau Likert scale (Vincent and Lewith, 1995). They administered this after three sessions but did not repeat at any other point in the 12 session, 17-needle protocol, finding both penetrating and non-penetrating interventions to be equal in credibility. However, the penetrating group were more confident, when compared to non-penetrating, that treatment would help ( $p=0.034$ ), though opinion on whether they had received acupuncture or not was similar between groups ( $p=0.802$ ). They adopted a VAS to measure pain intensity and another to assess PPGP discomfort for morning and evening pain, but only assessed them at the final point of contact (last treatment week). They found no difference for morning

( $p=0.288$ ) or evening ( $p=0.483$ ) VAS scores between the groups, though both groups were improved compared to baseline measurements. They also adopted the DRI, ODI and EQ-5D as outcome measures for ADL assessment, which Grotle *et al.* (2012) found to be appropriate for PPGP.

For DRI measurement, there was a difference ( $p=0.001$ ), with the penetrating acupuncture group demonstrating greater reductions in disability. For ODI ( $p=0.479$ ) and EQ-5D ( $p=0.511$ ), there were no differences between the groups after treatment. The authors conclude that they thought acupuncture to be a valuable intervention, more so that the penetrating group were able to function at a greater level compared to their non-penetrating counterparts. They support this by discussing the acupuncture ritual that would have been very similar in both groups and how this may influence reported outcomes. In addition, because regular work was not controlled for across groups in Elden *et al.* (2008), it could also be considered an impacting factor, as rest is often considered a method of helping to manage symptoms of PPGP (Elden *et al.* 2008). Finally, the confidence that treatment may work could have impacted upon results, either to inflate the impact of penetrating acupuncture or to reduce believability in the non-penetrating group.

Because of the limitations of Elden *et al.* (2005) through non-measurement of credibility, and Elden *et al.* (2008) failing to achieve homogeneity of the groups, further work is warranted to investigate acupuncture impact upon PPGP. In addition, the outcome measure for ADL's adopted by Elden *et al.* (2008) are not PPGP specific, and thus it is debatable as to whether the DRI and ODI would measure symptom change accurately. Elden *et al.* (2008) are also the only study to have used EQ-5D to measure general wellbeing, so it remains unclear as to whether this is warranted for a PPGP study. These issues were

identified and acted upon in the feasibility study in Chapter 7. However, it would also appear that there is no consistency as to what is the best acupuncture approach, with all studies appraised so far adopting various body acupuncture techniques.

A literature search for KHA found nothing for PPGP or LBPp, but did find two studies investigating KHA for CLBP. Lim and Yi (2003) compared a control group to a KHA group over a 4-week period. They found that pain and ADL difficulty, both outcomes that are typically measured in PPGP research, were significantly improved in the KHA group compared to the control. A more recent study supported these findings, in which Yang (2009) compared 40 participants, 18 in the KHA group and 22 in the control group. This trial concluded that KHA was more effective for treating CLBP in a 4-week period than the control group. However, further potential rationale for the use of KHA for PPGP can be found when looking at research of other microsystem acupuncture.

The only study to investigate acupuncture impact on LBPp and PPGP through a micro system approach is Wang *et al.* (2009), who investigated auricular acupuncture, utilising a VAS for average level of pain, and the DRI. They took demographic data, including maternal age and gestational age, education level as well as measures of previous LBP. They recruited 159 women to one of three groups: standard care plus acupuncture, standard care plus sham acupuncture, or standard care alone. They found that all participants reported improvements from baseline in VAS and DRI ( $p < 0.001$  for both outcomes), with the acupuncture group reporting better outcomes on the VAS compared to the sham group ( $p = 0.001$ ) and standard care group ( $p < 0.001$ ). For DRI, the acupuncture group produced larger improvements to disability compared to sham ( $p = 0.03$ ) and standard care alone ( $p = 0.001$ ). However, data were only collected over a two week pe-

riod, though were collected at three points (baseline, midway and at one week post treatment). By collecting at three data points, the researchers could show how treatment progressed over time, as opposed to a single measurement at the end of treatment, as with Elden *et al.* (2005) and Elden *et al.* (2008).

Wang *et al.* (2009) also reported homogeneity for baseline demographics and credibility of treatment, though these were not assessed for the standard care group. If treatment belief was different between the control and acupuncture groups, this could have led to the differences between the outcomes recorded, and thus should have been measured. As this paper is the only published micro system approach to PPGP, and was a pilot study, it was initially considered as the most appropriate to follow for the feasibility study outlined in Chapter 7.

Finally, Ekdahl and Petersson (2010) investigated if the timing of when acupuncture was administered in PPGP and LBPP sufferers made a difference to pain and function scores. Using a VAS, SF-36 and SF-MPQ, followed by telephone interviews, this paper appears to be the only mixed methods approach to investigating acupuncture within PPGP. Both groups received acupuncture, one group receiving it at gestational week 20, the other at gestational week 26, and had between 8-12 sessions in a six week period. The outcome measures were taken at each treatment session, meaning each outcome was assessed eight times. The researchers found that onset of PPGP was on average at week 13-14, with nine drop outs across the two groups because of premature contractions, illness, beneficial effects of the treatment or gave no reason.

They found that the group who started acupuncture later reported lower mean pain scores ( $p=0.001$ ), greater improvements from baseline to final session ( $p=0.003$ ) and

lower pain experience scores ( $p=0.016$ ) when compared to the earlier group. They also found that the earlier group did not have a significant difference in VAS scores comparing baseline to final session ( $p=0.56$ ), though both groups demonstrated significant improvements to pain experience scores in the SF-MPQ ( $p=0.001$ ). The weaknesses to this study are that they only used one test for PPGP (P4), despite it being advocated by Kanakaris, Roberts and Giannoudis (2011) as one of many tests that should be performed, and the reporting of baseline demographics is only provided appropriately for mean age and outcome scores, of which they were homogenous. This is at odds with other high quality studies such as Wang *et al.* (2009) and Elden *et al.* (2008), as other demographics are considered to potential impact upon outcome (Bishop and Lewith, 2008). The quantitative data was supplemented by qualitative findings, in which women frequently stated that they had found acupuncture to be beneficial and helped them to cope with PPGP for the remainder of the pregnancy.

The qualitative phase is brief, though does provide validity to the quantitative findings whilst providing additional information that would have not been reported upon through quantitative measures. The mixed methods approach is supported by the MRC framework for complex interventions (Craig *et al.* 2008) and is discussed in further depth in Chapter 4, providing a solid rationale for adopting it for the overarching method for this thesis.

**Table 3: Study characteristics in controlled trials of acupuncture for LBPp and PPGP**

Study	Design	Interventions (mean age in years)	n	Diagnosis	Defined by	Gestation in weeks when intervention first administered	Outcome measures adopted	Outcome of between group comparisons
Da Silva <i>et al.</i> , (2004)	CCT	1. ACU (27) 2. Pain medication only (25)	61	LBPp and PPGP	Unclear	15-25	<ul style="list-style-type: none"> <li>NRS for pain and functional tasks</li> </ul>	<ul style="list-style-type: none"> <li>Reduced pain (p=0.01) and increased function (p=0.01) in ACU compared to pain medication only</li> </ul>
Ekdahl and Petersson, (2010)	RCT	1. ACU at 20 weeks gestation (28) 2. ACU at 26 weeks gestation (28)	40	LBPp and PPGP	P4 test	20-26	<ul style="list-style-type: none"> <li>VAS for pain</li> <li>SF-36</li> </ul>	<ul style="list-style-type: none"> <li>ACU at 26 weeks reported less pain</li> </ul>
Elden <i>et al.</i> (2005)	RCT	1. SE (31) 2. SE + ACU (31) 3. SE + Stabilising exercises (30)	386	PPGP	P4 test; FABER's test; modified Trendelenburg test; ASLR; palpation of SPJ	12-31	<ul style="list-style-type: none"> <li>VAS for pain</li> <li>Assessment of PPGP severity</li> </ul>	<ul style="list-style-type: none"> <li>Reduced pain in SE+ACU when compared to SE (p=0.001), no difference when compared to SE + stabilising exercises.</li> <li>Severity of PPGP reduced in ACU+SE compared to SE and SE + stabilising exercises</li> </ul>
Elden <i>et al.</i> (2008)	RCT	1. SE + ACU (31) 2. SE + npACU (30)	115	PPGP	P4 test; ASLR	12-29	<ul style="list-style-type: none"> <li>DRI</li> <li>EQ-5D</li> <li>VAS for morning pain</li> <li>VAS for evening pain</li> <li>ODI</li> </ul>	<ul style="list-style-type: none"> <li>DRI reduced in SE+ ACU when compared to SE+npACU</li> <li>EQ-5D was no different p=0.511)</li> <li>VAS for morning (p=0.288) and evening (p=0.483) pain were no different</li> <li>ODI demonstrated no change (p=0.479)</li> </ul>
Kvorning <i>et al.</i> (2004)	RCT	1. ACU (30) 2. Standard care (30)	72	LBPp and PPGP	Unclear	26-34	<ul style="list-style-type: none"> <li>VAS for pain and functional tasks</li> </ul>	<ul style="list-style-type: none"> <li>Reduced pain (p=0.01) and increased function (p=0.001) in ACU when compared to Standard care</li> </ul>
Lund <i>et al.</i> (2006)	RCT	1. Superficial ACU 2. Deep ACU	70	LBPp and PPGP	1 of 3: P4 test, modified Trendelenburg, FABER's; palpation over SIJs, SPJ,	22-36	<ul style="list-style-type: none"> <li>VAS</li> <li>NHP</li> </ul>	<ul style="list-style-type: none"> <li>Non-significant differences between groups, no statistics reported</li> </ul>

**Table 3: Study characteristics in controlled trials of acupuncture for LBPp and PPGP continued**

Study	Design	Interventions (mean age in years)	n	Diagnosis	Defined by	Gestation in weeks when intervention first administered	Outcome measures adopted	Outcome of between group comparisons
Wang <i>et al.</i> (2009)	Pilot RCT	1. aACU (33) 2. npaACU (32) 3. usual care (32)	159	LBPp and PPGP	Unclear	25-38	<ul style="list-style-type: none"> <li>VAS for pain</li> <li>DRI</li> </ul>	<ul style="list-style-type: none"> <li>Reduced pain (p=0.001) in aACU when compared to npaACU and usual care</li> <li>Increased function in aACU compared to npaACU (p=0.03) and usual care (p=0.001)</li> </ul>
Wedenberg, Moen and Norling (2000)	RCT	1. ACU (28) 2. Physiotherapy (29)	60	LBPp and PPGP	Provocation tests, specifics not reported	20-32	<ul style="list-style-type: none"> <li>NRS for pain</li> <li>DRI</li> </ul>	<ul style="list-style-type: none"> <li>Reduced pain in ACU compared to Physiotherapy (p=0.01).</li> <li>DRI improved in ACU compared to Physiotherapy in 11 out of 12 items, no statistics reported</li> </ul>

n = number of participants; RCT = randomised controlled trial; P4 = posterior pelvic pain provocation test; ASLR = active straight leg raise; LBPp = pregnancy-related lower back pain; PPGP = pregnancy related pelvic girdle pain; VAS = visual analogue test; SI = sacroiliac; SPJ = symphysis pubis joint; SE=standard exercises; aACU = auricular acupuncture; ACU= body acupuncture; npaACU= non-penetrating auricular acupuncture; npACU= non penetrating acupuncture; CCT= controlled clinical trial; DRI= disability rating index; ODI=Oswestry disability index; NHP=Nottingham Health Profile



There are existing studies that have looked at the collective strength of the acupuncture in PPGP literature. A systematic review by Ee *et al.* (2008) looked to establish the quality of evidence base for the use of acupuncture in LBP/PGP during pregnancy. The authors only included RCT's that compared acupuncture to non-penetrating interventions, such as placebo acupuncture or exercise, totaling three: Wedenberg *et al.* (2000), Kvorning *et al.* (2004) and Elden *et al.* (2005). They looked to review pain, disability, amount of analgesics taken, time off work and adverse events. The review highlighted that there is a need for further high quality research into the area for acupuncture in LBPp /PPGP, as although the results within the three articles were promising, the methods were high quality in two (Kvorning *et al.* 2004 and Elden *et al.* 2005) and poor in another (Wedenberg *et al.* 2000). The conclusions for this review are supported by the Vleeming *et al.* (2008) European guidelines for PGP and the Cochrane review on LBPp and PPGP by Pennick and Liddle (2013), who also reported acupuncture to have promising evidence yet requiring further high quality research.

The Pennick and Liddle (2013) review gave specific focus to acupuncture for pelvic pain, as well as studies that investigated a combination of LBPp/PPGP. They reported low quality evidence in two studies (Elden *et al.*, 2008; Lund *et al.*, 2006) and moderate quality evidence to support acupuncture over exercise for evening pain (Elden, 2005) when focusing solely on PPGP. Only low quality evidence was found when acupuncture studies combined LBPp and PPGP, yet in comparison to other existing modalities, acupuncture fared better in study quality and outcome stakes. Thus, Pennick and Liddle (2013) advocate acupuncture in the treatment of PPGP.

Close *et al.* (2014), in their systematic review of RCT's, put forward that acupuncture appears to be a useful intervention for PPGP and LBPp, though reported that only two

studies (Elden *et al.* 2005; Elden *et al.* 2008) had statistically and clinically significant results as well as low risk of bias. Gutke *et al.* (2015) provided a wider scope literature review that reported on all studies that investigated physiotherapy techniques for women who had PPGP and/or LBPp. They found seven acupuncture RCT's, one long term follow up study and one controlled clinical trial study which were of good methodological quality and that demonstrated acupuncture to reduce pain and increase function (Gutke *et al.* 2015). They concluded that there was strong evidence to support acupuncture for the treatment of pain in the lumbopelvic region.

### **3.7 Outcome measures**

Either the VAS or NRS are used as outcome measures in all of the studies outlined in Table 3, with both considered to have excellent test retest, construct validity and have a high correlation with one another (Hawker *et al.* 2011). In particular, the NRS has an excellent ability to detect change with a reduction of 2 points considered clinically important (Hawker *et al.* 2011). The use of the NRS is therefore an appropriate outcome measure to assess pain, and has been included within the feasibility study outlined in Chapter 7, to partially measure KHA effectiveness. However, unlike the NRS, ADL outcome measurement use in PPGP studies carries a level of discrepancy.

One common flaw with all of the previously discussed studies is the failure to use a PPGP specific outcome measure, something which Stuge *et al.* (2011) developed, and can be used in research and clinical practice for PPGP. The authors pointed out that in previous research, LBP outcome measures have been used but which have not been validated for PPGP. Stuge *et al.* (2011) developed the Pelvic Girdle Questionnaire (PGQ) by initially identifying no existing outcome measure in the published literature, followed by a semi-structured focus group of PPGP and ppPPGP sufferers. The issues that

were identified as troublesome began to populate a list of items, and were added to by the lead author extracting items from frequently used outcomes measures (RMDQ, ODI and the DRI) that were thought to be relevant to PPGP. This was then followed up by asking physiotherapists to add to the existing list, through asking their patients to write down issues that they found most troublesome. This process was conducted in order to give content and face validity, which were assessed through the International Classification of Functioning, Disability and Health (ICF), and produced 46 items.

This early PGQ was then used with a small pilot study of five PPGP and five ppPPGP sufferers, who were asked to provide a response on a five-point Likert scale for each of the items developed, and provided suggestions on slight alterations to wording. Finally, psychometric testing of validity and reliability was conducted through postal questionnaires on those diagnosed with PPGP, initially with 52 PPGP and 42 ppPPGP sufferers, and after revision, with 43 PPGP and 44 ppPPGP. Stuge *et al.* (2011) reported that there were very low levels of missing data and no participants suggested that any item was not applicable. They did a test retest reliability assessment on 21 women from PPGP and 21 from ppPPGP groups, with a final five PPGP sufferers asked to comment on the final version of the PGQ. The 46 item list was reduced after rasche analysis to 25 items due to redundancy and similarity of questions, with each five point Likert type item being reduced to four points instead. Stuge *et al.* (2011) found that their 25-item PGQ, which did have content and face validity whilst also demonstrating reliability, had no items that were the same as any of the other previously used outcome measures. As a result, the authors argue that the PGQ is the most appropriate for use in clinic and within research across differing cultures.

Further support for the PGQ is noted in Grotle *et al.* (2012), where the PGQ was completed alongside five other outcome measures commonly used in PPGP research (ODI, DRI, SF-36, Fear Avoidance Beliefs and Pain Catastrophising Scale) assessing test-retest reliability. They found that there was good level of test-retest reliability, internal consistency and construct validity for all outcomes. However, as the authors recognised, the responsiveness to change value of the PGQ outcome measure was not assessed.

Grotle *et al.* (2012) advocated the use of the PGQ in clinical and research practice. For this reason, the researcher here considered it necessary to include it as a secondary outcome measure in Chapter 7. However as acupuncture gains increasing popularity in western society, its effects are the focus of western medical scrutiny prompting a surge of research interest (Kawakita *et al.* 2006). The western theoretical underpinning of how acupuncture works is still under debate, with most researchers turning to peripheral and central pain structures to try to explain how acupuncture pain relief works.

### **3.8 Acupuncture mechanisms**

Nociception is the term given to the result of nociceptors being activated through strong noxious stimuli (chemical, mechanical or thermal), which have the potential to cause tissue damage (Silverthorn, 2010). Nociceptor activation is modulated by local chemicals that are released upon tissue injury, such as prostaglandins, substance P and Calcitonin Gene Related Peptide (Backer and Hammes, 2010). These chemicals also mediate the inflammatory response, by either activating the nociceptors, or lowering their action potential threshold (Silverthorn, 2010). Afferent signals are carried from nociceptors to the central nervous system (CNS) via A-Delta, A-beta and C fibres (McMahon *et al.* 2013). On subjection to sufficient stimulus, a peripheral nerve would be activated to send an impulse along its pathway to the dorsal horn. The response is to fire a message back to the

affected area, creating the production of substance P and Calcitonin Gene Related Peptide, two chemicals that are pro inflammatory, and therefore, stimulate chemoreceptors to continue to send messages to the dorsal horn, maintaining a pain loop (Backer and Hammes, 2010).

Simultaneously, any pain message that reaches the dorsal horn is also sent up ascending pathways to the brain, in particular the sensory cortex and thalamus, hypothalamus and limbic system. This allows “making sense” of the stimulus (Silverthorn 2010), with pain centre’s then sending messages down descending pathways to the relevant dorsal horn, and as with the pro inflammatory mediators in the periphery, maintain the pain process. Pain relief through medication often comes in the form of inhibiting pro-inflammatories, presumably slowing the transmission of a pain-creating stimulus to the CNS (Silverthorn, 2010). Opioid drugs act directly on CNS opioid receptors, these block neurotransmitter release from primary sensory neurons (such as substance P creating neurons). It can also have effects on beta-endorphin release from the hypothalamus (Silverthorn, 2010), which is part of the limbic system.

The limbic system, a primitive part of the brain which resides in most animals, is primarily involved in making sense of stimuli, and in effect, attaching emotional and mental processes to such stimuli (Lund, Naslund and Lunderg, 2009). This is important in survival; if the individual interprets a potentially harmful stimulus as pain, and therefore associates said stimulus with fear, they are less likely to seek out that stimulus again, and likely to try and avoid it (Silverthorn, 2010). This is an important survival tactic, but can become overactive in certain instances, such as in chronic pain. Several studies have shown parts of the limbic system, in particular the Amygdala and Hippocampus, to be more active in those who suffer with chronic pain, than in the non-chronic pain population

(Dhond *et al.* 2008). This lends support to current theories around the maintenance of pain through central brain systems, and not necessarily from peripheral neuropeptide presence (Dhond *et al.* 2008).

The specificity of acupuncture effect is not so well defined, with conflicting research findings on acupuncture being superior to placebo (more of which will be discussed later in this chapter). Despite its origins in TCM, acupuncture has a large presence within western medicine, with numerous mechanisms being proposed for how it works. It is believed that acupuncture influences neurohumoral, descending pain and diffuse noxious inhibitory control (DNIC) mechanisms (Elden *et al.* 2008), as well as having a direct influence on important pain centres within the brain (Hui *et al.* 2011), impacting upon opiodergic and monoaminergic systems (Dhond, Kettner and Napadow, 2007). In addition, down regulation of the limbic system has been noted in several studies (Dhond, Kettner and Napadow, 2007; Dhond *et al.* 2008; Huang *et al.* 2012). A meta-analysis by Huang *et al.* (2012) found that despite the quality of reporting in fMRI studies that looked into acupuncture's impact on specific brain areas, there is a strong suggestion that acupuncture can stimulate specific areas of the brain (Huang *et al.* 2012). The influence acupuncture has on the limbic system could explain why patients report less anxiety and concern surrounding their pain.

A more generalised analgesic effect can be seen through DNIC, whereby brain centres such as the Peri Aqueductal Gray (PAG) can give generalised pain relief throughout the body (Le Bars, 2002). Pain inhibition through the mechanism of DNIC is triggered by a part of the body that is away from the area affected by pain (Le Bars, 2002). It is thought that DNIC is triggered by A delta and C fibres. C-fibres only innervate the hairy side of

the skin, such as the dorsum of the hand, and convey the messages which evoke emotions to pain (McMahon *et al.* 2013). A-delta fibres, also found on the dorsum of the hand, conduct messages such as sharp pricking sensations (McMahon *et al.* 2013). The hand is considered to have one of the most dense population of A and C fibres in the body (McMahon *et al.* 2013) making it an ideal candidate to stimulate the DNIC response, and brain pain centres. However, the placebo mechanism is something which is poorly understood, yet is considered to be a potential explanation for why individuals experience symptom relief through acupuncture.

### **3.9 Background to placebo**

The words placebo and placebo effect have been synonymous with health-based research for well over a century (Sharipo, 1968). Placebos are wittingly and unwittingly included into all health-based research, with the placebo effect often being reported upon as a substandard outcome (Madsen, Gotzsche and Hrobjartsson, 2009). Whether this is intentional or not remains to be seen; however, it would appear that there is confusion as to what a placebo is (perhaps because the word means different things to different people) and the importance of the placebo effect. In particular, the reporting of what has caused the placebo effect is generally woeful in comparison to the supposed “independent variable” effect. Clinicians and researchers alike would appear to understand the concept of placebo, and on discussion, most will be able to point to numerous variables that may have led to an observed effect of symptoms, yet specific variables in addition to the independent variable being investigated are rarely discussed in research papers. Placebo acupuncture is a common term to describe an intervention that closely mimics acupuncture. It is usually separated into methods which needle non acupoints or known acupoints at a very shallow depth (penetrating placebo), which is testing TCM acupuncture theories of location of acupoints (Lund, Naslund and Lundeborg, 2009), or a non-

penetrating placebo method, where the investigation surrounds the importance of needle insertion. In both these scenarios, labeling the non-traditional approaches as placebo, rather than penetrating or non-penetrating, does not accurately describe what is being administered.

Hopton and MacPherson (2010) performed a systematic review of pooled data from meta-analyses, finding that acupuncture treatment groups consistently performed better than their placebo counterparts. Although briefly acknowledged as a limitation, this study serves to demonstrate a point of the poor reporting of placebo, indicating a 'combined range of sham (placebo) interventions' (Hopton and MacPherson, 2010). This means that many variables are not being considered as potential impacting factors, and that in their analysis, penetrating needles in non-acupuncture points are the same as non-penetrating acupuncture. Prior to establishing a credible non-penetrating KHA approach through Chapter 5 and 7, it is first important to outline exactly what a placebo and the placebo effect are, and why it is of utmost importance to report exactly why observed changes could have occurred, rather than simply labeling any effect that cannot be attributed to the independent variable as placebo.

Shapiro (1968) attempted to clarify the original meaning of the word 'placebo' in a healthcare context, discounting several incorrect interpretations before suggesting it 'a commonplace method or medicine' (Shapiro, 1968, p.682). Brody (1982) suggested that the use of placebo's in medicine in the 1800's was well established, pointing to several texts describing medicine at the time as using 'bread pills' as part of genuine medical practice. When placebos were administered, it was as a soother to the patient, with the belief that a placebo treatment could not yield any physiological effect, and only those



that were less intelligent were likely to gain benefit (de Craen *et al.* 1999). However, con-men who sold lotions and potions in the 1800's seemingly tarnished the word placebo, as researchers began to test the proclaimed curative properties of such remedies against known drugs and found them to have little or no effect (de Craen *et al.* 1999). With the “prescriber” fully aware of its inability to do such things, these potions and lotions were indeed the tool of deception and fraud. This led to an evolved definition of the word placebo by the mid twentieth century, to describing it as an inert intervention, and one that is delivered in fraudulent terms (Shapiro, 1968).

The ritual of an intervention has been considered and investigated as an impacting factor upon symptoms, and so historically when researchers attempt to investigate whether an intervention had an active ingredient to it, they would provide an intervention that was supposedly inert, but mimicked the true intervention (Shapiro, 1968). In acupuncture studies, this has involved a sham acupuncture approach, which adopts either a skin penetrating or non-skin penetrating method as the placebo arm. If changes are observed in the mimicked group, it is often reported as a result of placebo; if the changes are similar when compared to the “real” intervention, researchers often conclude that the treatment is no better than placebo (Madsen, Gotzsche and Hrobjartsson, 2009).

An example of a variable which can impact upon the performance of an intervention is the Hawthorne effect (Bowling and Ebrahim, 2005). The act of an individual being observed can impact upon symptoms and symptom reporting, so researchers often attempt to control for this by ensuring the “placebo” and intervention group have the same amount of supervised time (Bowling and Ebrahim, 2005). It therefore stands to reason that if the Hawthorne effect is not adequately controlled for, any improvements to pain could be partially or wholly attributable to the Hawthorne effect, reducing the confidence

a researcher may have in, for example, penetrating KHA (pKHA) being the cause of improvements to pain symptoms. Therefore, the study put forward in Chapter 7 compared two groups which had the same amount of contact time, to eliminate the Hawthorne effect as an independent variable. Yet other factors, such as natural progression of a disease, can also impact upon research findings.

By the turn of the 20th century, placebo trials became more widespread, with one of the larger comparative study's investigating diphtheria and the impact of an anti-toxin versus placebo, concluding that similar outcomes were noted between the placebo and true groups (de Craen *et al.* 1999). This was followed by a placebo controlled study investigating cold vaccines, finding the placebo group producing the same level of results as other non-controlled trials which had previously supported the use of a vaccine. Despite widespread belief that the placebo effect of a placebo was 35%, Kienle and Keine (1997) refuted that claim, since potential factors such as natural progression of the disease were often not investigated in placebo controlled studies. Kienle and Keine (1997) suggested that there were potentially 19 other factors that could have led to the positive effects in the placebo group, therefore ruling out the 35% placebo effect.

Yet, in PPGP, where there have been treatments noted to improve symptoms, it would be unethical to deny a group of individuals treatment for the benefit of observing the natural progression of the condition. As will be discussed in Chapter 7, any improvements noted for within group comparisons could be due to natural progression of PPGP, although the findings from Kvorning *et al.* (2004) and Da Silva *et al.* (2004) would suggest, if anything, symptoms progressively worsen. It is, therefore, important to attempt to control for as many different variables as possible, hence why research such as that conducted in Chapters 5 and 7, aimed to collect baseline demographic data and have two

interventions that were very similar in execution.

### **3.10 Physiology of placebo acupuncture**

The consideration of placebo as an intervention that appears credible, but has no known active agent within it (i.e. an inert procedure), is no longer accurate. Placebos have been demonstrated to elicit a physiological response and, therefore, cannot be considered inert (Finniss *et al.* 2010). For example, the present day understanding of needle insertion is that placing a needle anywhere in the body induces physiological responses through a variety of mechanisms, including local alteration of circulation and immune function, neurophysiological and neurochemical changes (MacPherson *et al.* 2007). However, pressure over the skin has also been shown to have some physiological response, albeit not as pronounced as when a needle is inserted (Lund, Naslund and Lundeberg, 2009).

Harris *et al.* (2009) considered whether penetrating acupuncture produced a physiologically different response to a non-penetrating acupuncture approach. They looked at opioid receptor activation in 18 female fibromyalgia sufferers, measured through Positron Emission Tomography (PET). Their findings showed that at both short and long term follow up, where penetrating acupuncture activated endogenous opioid anti-nociceptive system availability, the non-penetrating approach did not, or actually reduced it slightly. However, both groups reported the same amount of pain relief, suggesting that the pain relieving effect may originate from another, unknown pain mediating system, and is supported by other studies.

Chae *et al.* (2009) conducted a study on ten healthy right handed subjects, to find if there was a difference on fMRI between placebo and true acupuncture. The placebo approach was a non-penetrating needle. A cross over design was used, so all participants received penetrating and non-penetrating acupuncture without being told what they were

receiving. The authors measured allocation concealment, and found that participants could not differentiate between penetrating and non-penetrating acupuncture ( $p=0.139$ ). The study also found numerous brain areas had a significantly higher activation when compared to baseline ( $p<0.001$ ) but that the penetrating approach elicited more activity when compared to non-penetrating acupuncture ( $p<0.001$ ). Because the two acupuncture approaches were indistinguishable to the participants, the authors contended that the changes in brain activity can be put down to specific physiological effects of penetrating acupuncture. This advocates the use of penetrating forms of acupuncture, such as pKHA, whilst supporting the need to investigate a credible and believable npKHA approach to control for Hawthorn effect.

Cherkin *et al.* (2009) performed an RCT which included penetrating acupuncture and non-penetrating acupuncture (which was labeled placebo acupuncture), aiming to investigate whether acupuncture benefits to symptoms of pain and function for CLBP were due to a placebo response. When penetrating and non-penetrating forms of acupuncture were compared to control only, the acupuncture groups were statistically significantly better for pain and function ( $p<0.001$ ). Because there had been positive effects, but it appeared that penetrating the skin was not needed to achieve this, the authors labeled the positive effect as a result of a placebo (Cherkin *et al.* 2009). However, this did not enlighten the reader any further as to what caused the improvement, and because the authors had controlled for several other known variables, it would have been more helpful to label that the benefits were likely as a result of an unknown variable, or due to the ritual of acupuncture.

Harris *et al.* (2009) and Chae *et al.* (2009) highlighted that penetrating and non-penetrating forms of acupuncture can be considered indistinguishable to the participant, yet elicit

different physiological responses. This suggests that believability of an intervention can be controlled for when using a non-penetrating method, yet the penetrating approach may have additional benefits. At this point, the definition put forward by Shapiro (1968, p.682) on placebo classification: “it is something that has an effect on a patient, symptom, syndrome or disease, but which is objectively without specific activity for the condition being treated”, can be rejected, as a placebo can elicit a physiological response. Perhaps a more accurate definition of a placebo would be “an unknown variable, or combination of unknown variables, that impact upon a person’s symptoms.”

### **3.11 The placebo effect**

For an intervention to be considered a placebo, it must produce improvements to symptoms, i.e., the placebo must produce a placebo effect. Shapiro (1968, p.682) defined the placebo effect as a ‘psychological or psychosocial effect produced by placebos’. Brody (1982, p.113) considered it a ‘change in symptoms based purely on the interventions import rather than the pharmacological or physiological effect of the intervention.’ However, Kaptchuk *et al.* (2010) put forward that researchers should look to not only account for placebos causing improvements to symptoms, but actively encourage their inclusion to the clinical environment wherever possible, because regardless of the mechanism, the patient demonstrates improved outcomes when placebo’s are at work. Within this context, there have been a number of researchers who have investigated what factors could lead to the placebo effect.

The personality of the placebo responder has been investigated to determine whether it is a factor in the placebo response. Since the inception of the placebo trial, there has been a long held view by researchers and clinicians that either intelligence or specific

personality traits have a large role to play in the placebo effect (Wasan *et al.* 2010). Wasan *et al.* (2010) investigated 40 CLBP patients, separating them into those who had high psychopathological scores and those who had low psychopathological scores. They claimed that those with higher scores tended to fair less well than those with lower scores in acupuncture analgesia, with their hypothesis being that those with higher psychopathological scores will be more susceptible to having a greater placebo effect (Wasan *et al.* 2010). They did not elaborate on what they considered as psychopathological, suggesting a wide range of interpretation, reducing the study's internal validity.

The penetrating approach was to insert a needle into an acupuncture point, and the non-penetrating approach was to use a stage dagger type needle. They found for both high and low psychopathological group scores, the change in pain was very similar ( $p=0.90$ ), with both groups improving. The authors concluded that, contrary to their hypothesis, psychopathology could not be used as an adequate predictor for those who would respond more or less to a placebo approach (Wasan *et al.* 2010). It would, therefore, seem that the psychological state or belief's that an individual holds has little impact upon the amount of placebo effect noted, which dismisses the definitions made by Shapiro (1968) and Brody (1982). This provides a rationale for not attempting to control for psychopathological scores within the studies outlined in Chapter 5 and 7.

Another variable that appears to influence treatment outcome is the therapist-patient relationship. Kaptchuk *et al.* (2008) investigated irritable bowel syndrome, including 262 adults over a three to six week period, and measured symptom severity, quality of life and adequate symptom relief. They found that when a placebo acupuncture treatment was combined with an augmented interaction between therapist and patient for irritable bowel syndrome, the outcomes were far greater than when a placebo was administered

with minimal therapist-patient contact, or a waiting list control group. In essence, attention to the patients' issues, and the empathetic approach, yielded a much greater improvement to symptoms than when the patient was met with a more reduced interaction. Although Kaptchuk *et al.* (2008) were unable to state the variable(s) within empathetic attention that produce such improvements, they concluded that including empathetic approaches were more likely to lead to better outcomes.

If a placebo was defined purely by its ability to provide benefits to health through treatment expectation, then one would expect the placebo effect to be constant, no matter what the placebo intervention was. Linde *et al.* (2010) made an interesting conclusion on their analysis of placebo acupuncture against other placebo interventions. They not only found acupuncture placebo, in this case non-penetrating acupuncture, to have larger effects than pharmaceutical placebos when compared to control groups, but also that when compared to other non-pharmacological placebo interventions, acupuncture placebos create larger effects ( $p=0.007$ ). With treatment expectation controlled for across all four groups, this highlighted that treatment expectation is not the sole mechanism behind how a placebo works. However, the paper does serve to highlight that treatment expectancy, which could be informed by believability and credibility, are potential factors that could effect symptom changes. Therefore, believability of any placebo non-penetrating form to KHA should be investigated prior to any inclusion in a large-scale study; Chapter 5 aimed to do this.

Kaptchuk *et al.* (2006) investigated whether one placebo approach had a larger impact on pain than another placebo approach. The two placebo approaches were investigated by nesting a study within two separate studies, which both investigated a repetitive strain

upper limb disorder. One RCT compared penetrating acupuncture to non-penetrating acupuncture, the other amitriptyline to a placebo pill. The acupuncture study received treatment twice a week in both groups, the amitriptyline trial a pill everyday with researcher follow up via telephone every other week. The results demonstrated a significant difference in favour of placebo acupuncture over placebo pill, when it came to amount of pain relief attained ( $p=0.001$ ) and symptom severity ( $p=0.02$ ). Although there were no serious adverse events noted, a quarter of the placebo acupuncture group and a third of the placebo pill group reported adverse events that were specific to the list of potential adverse events that they were told about in the informed consent procedure (i.e., different adverse events were noted in the placebo acupuncture group to the placebo pill group).

Both Linde *et al.* (2010) and Kaptchuk *et al.* (2006) highlighted the importance of considering a placebo and its effect in a much greater depth when conducting research. There is an abuse of the word placebo when reporting effects, and the importance of the placebo has changed over time. As with the word placebo, the problem of using the words placebo effect lies in the interpretation by researchers and readers of research. Due to the misinterpretation and stigma that is attached to the words placebo effect, it is perhaps prudent to instead encourage authors to be more specific in their description of potential reasons for change to symptoms. At the very least, the words placebo and placebo effect should be reserved for only those variables and their associated effects that are unknown to the researcher, and thus a more accurate definition of the placebo effect is a more realistic aim than to rid the scientific world of its terminological use. Therefore a suggestion for a revised placebo effect definition is put forward: 'the positive subjective and/or objective change of symptoms, where the exact independent variable(s) remain unknown.'



However, one factor that is consistent through most placebo based research is that the placebo intervention must be considered by the recipient as indistinguishable from the true intervention (Vincent and Lewith, 1995). The study outlined in Chapter 5 will investigate the believability of a non-penetrating KHA approach, though the importance of distinguishability needs to be first considered.

### **3.12 Distinguishability**

If one group has an intervention delivered and another group does not, despite both being observed by a researcher, it is very likely that the group that has not received an intervention will know that they have not. This can lead to the treatment expectancy effect, whereby the fact that the individual knows that they have not received treatment impacts upon their pain (Bowling and Ebrahim, 2005). Or put another way, if an individual thinks that they have had treatment, the treatment expectancy effect can improve pain scores. With this in mind, researchers wanting to investigate acupuncture effectiveness often provide two groups: one who receives the true intervention, the other who receives a fake intervention, commonly referred to as a placebo (MacPherson *et al.* 2007). The Hawthorne effect is nullified, whilst the treatment expectancy effect is also dealt with, as long as the participant feels they have received the intervention. Madsen, Gotzsche and Hróbjartsson (2009) performed a systematic review of studies that compared acupuncture to placebo acupuncture for pain. They found very little difference between placebo (both penetrating and non-penetrating) acupuncture and ‘true’ acupuncture, and postulated that the differences could have been due to an unblinding of the placebo groups. Put into context for this thesis, if a participant does not believe that they have received KHA, it could lead the non-penetrating group to have a reduced treatment expectancy, and therefore influence the results recorded.

Smith and Crowther (2002) investigated the credibility of a penetrating placebo acupuncture for those pregnant women who were suffering with nausea and vomiting in early pregnancy. It was found that those who received TCM acupuncture would more likely recommend acupuncture to a friend than those randomised into the placebo group ( $p = <0.01$ ) and more likely to recommend acupuncture in a group that had acupuncture in a true acupoint as opposed to a non acupoint ( $p = <0.05$ ). However, there was a considerable element of potential unblinding, as when compared to TCM ( $p = <0.0001$ ) and true acupoint ( $p = <0.01$ ), the placebo group recorded, on average, less times that they thought they had received a true intervention. Relief of symptoms was the primary reason why individuals felt they were assigned to a true acupuncture group, with the second most common reason for selecting that they had not received acupuncture was because of a lack of symptom relief. Needle sensation and treatment procedure (not expanded upon) was also noted as a reason for why they thought they had been allocated to a true acupuncture group. Therefore, the improved outcomes reported cannot solely be put down to the insertion of a needle, as it could also be the treatment expectancy effect. This lends support to the empirical study outlined in the methods section of Chapter 5, as the importance of developing a npKHA intervention that is indistinguishable from a penetrating approach allows for its inclusion into larger scale studies, and advocated its inclusion into the study in Chapter 7. In addition, it is important to record any reasons why an individual may or may not feel that they have received penetrating KHA, as it can help to inform study design.

Kong *et al.* (2006) investigated how expectancy influenced acupuncture analgesia. They used an fMRI on 77 acupuncture naive participants, 48 of whom completed the study and were included in data analysis to find if penetrating acupuncture and/or non-pene-

trating acupuncture had an impact on the amount of the noxious nature of a given stimulus. They found penetrating acupuncture gave stronger down regulation to important pain regions in the brain such as left insula/putamen/claustum/superior temporal gyrus and left inferior frontal gyrus. They found the placebo needle (non-penetrating) yielded comparable magnitudes of analgesia to penetrating acupuncture. They suggested that by purposely incorrectly informing participants of the level and area of relief, this influenced the reporting of relief. Despite this, however, the penetrating acupuncture group inhibited brain areas associated with pain interpretation, suggesting a pain inhibiting response, that was not found in the non-penetrating group. This shows that not only cognitive modulation, but also peripheral mechanisms, impact on acupuncture analgesia and that acupuncture analgesia may be enhanced by expectation. However, treatment expectancy has not always been shown to impact upon results.

Sherman *et al.* (2009) set out to investigate whether there were subgroups of patients who would respond better to acupuncture for CLBP. They used a nested study, situated within an RCT for CLBP and acupuncture (Cherkin *et al.* 2009), with 638 participants. Outcome measures taken were demographics, self-efficacy and expectation of acupuncture effectiveness, and severity of back pain. Along with finding increased severity of CLBP at baseline predicting larger improvement, they also found that pre-treatment expectations did not predict outcome. In support of this study, Kaptchuk *et al.* (2010) found that even when a group of individuals knew they were taking a placebo pill, therefore presumably eradicating the treatment expectation effect, the group still demonstrated statistically significant improvements to symptoms of irritable bowel syndrome when compared to baseline and a control of no intervention.

If expectation does play a role, producing a credible npKHA approach would help to control for a “credibility variable” between penetrating and non-penetrating KHA groups when testing for the value of KHA such as in the study in Chapter 7. Although as outlined above, the possibility of controlling for every possible variable that could impact upon an effect is near impossible, by neutralising the impact of a “credibility variable”, it helps to exclude credibility as a potential reason for differences between a penetrating and non-penetrating approach to KHA. Conversely, if the non-penetrating intervention had very little credibility, and the penetrating group had a higher level of credibility, credibility (and therefore expectation that the treatment will work) could be suggested as the reason for any differences noted between the two groups. Returning to the penetrating versus non-penetrating scenario, if the Hawthorne and treatment expectancy effect are controlled for, the researcher can be more confident that any changes in outcome are as a result of whether the needle penetrated the skin or not.

In order to determine whether a non-penetrating approach to KHA is credible, the recipients must think they have had KHA. This is not to say that participants must think they have received penetrating KHA, as a penetrating KHA group may not be completely convinced they have received penetrating KHA. However, there have been few studies that have discussed how to measure distinguishability between a penetrating and non-penetrating acupuncture intervention, but those that have are discussed further in Chapter 5. This gives a strong rationale for investigating the believability of a non-penetrating form of KHA (as investigated in Chapter 5), but also acknowledges the need to measure credibility in studies which look to measure the effect of acupuncture.

Vincent and Lewith (1995) advocated a modified version of a commonly adopted credibility scale by Borkovec and Nau (1972) when looking to measure the acceptability of acupuncture. The adapted scale is a Likert scale of four, 5 point Likert type items ranging from strongly agree to strongly disagree around:

1. "How confident do you feel that this treatment can alleviate your complaint?
  2. How confident would you be in recommending this treatment to a friend who suffered from similar complaints?
  3. How logical does this treatment seem to you?
  4. How successful do you think this treatment would be in alleviating other complaints"
- (Vincent and Lewith 1995)

Vincent and Lewith (1995) state that these questions can be "amended to take into account of the condition being treated and other circumstances of the trial." Vincent and Lewith (1995) found that when this scale was applied to the credibility assessment of receiving acupuncture, it produced good internal consistency. Smith and Crowther (2002) used this scale to measure credibility of their acupuncture and placebo acupuncture interventions. In the second phase of Sherman *et al.* (2002), they investigated non-penetrating acupuncture credibility using a credibility scale. Again, the results were that the non-penetrating form was as credible as the penetrating form. It is therefore possible to provide some measure of credibility of an intervention. By attempting to control for this variable, any research investigating the impact skin penetration has upon a patients symptoms can be more confident that their results are influenced by treatment credibility. Therefore, this scale was adopted in the study outlined in Chapter 7.

### 3.13 Chapter summary

There are a number of interventions that have been proposed and investigated for the treatment of PPGP, with the majority of literature supporting physiotherapy involvement. As previously presented, literature reviews such as Pennick and Liddle (2013) have indicated that currently, acupuncture has the highest quality research to support its use in PPGP. The acupuncture approach best suited to PPGP has yet to be established, with Elden *et al.* (2005), Elden *et al.* (2008), Wedenberg (2000) Kvorning *et al.* (2004) and Da Silva (2004) all using acupoints around the whole body, including the hand. However, the utilisation of a microsystem may yield greater improvements than body acupuncture, as the recipient does not have to adopt a static posture in lying or sitting for the duration of treatment, as they do with body acupuncture, due to the anatomical location of the needles. This is relevant to consider with PPGP, as the PGQ (Appendix 1) indicates the importance of static postures and movement associated with ADL's. Further support for microsystem acupuncture arises from Wang *et al.* (2009), who utilised this approach and reported benefits to pain and function ( $p = <0.03$ ) when auricular acupuncture was compared to a sham group and a standard care group. In addition, Vas *et al.* (2014) published a research protocol which demonstrates that they are also undertaking microsystem research for PPGP. Lim and Yi (2003) and Yang (2009) both found that KHA may help reduce pain and improve function in CLBP cohorts, and combined with proposed pain physiological mechanisms via DNIC and limbic activation, provides a rationale for investigating KHA impact upon PPGP.

Findings from Waterfield *et al.* (2015) indicates physiotherapists' reluctance to perform acupuncture on pregnant women, and, although not stated, one reason for this may be to do with needling around the lumbar spine and close to the pelvis. By introducing an acupuncture approach which requires needles to be placed away from the abdomen, it may

be considered a more desirable approach for physiotherapists over the usual body acupuncture approach, thus increasing its use with in pregnancy related pain. Bishop *et al.* (2015) would support this suggestion, as a third of physiotherapists use acupoints located on the hand. However, this has yet to be investigated, and thus Chapter 7 will look to explore the feasibility of investigating KHA effect on PPGP. It will do this through first developing a npKHA and pKHA method which as believable as one another, discussed in Chapter 5, before being implemented in Chapter 7. This is an important step to reduce potentially impacting variables, such as the Hawthorne effect and treatment expectancy, influencing any results gained. It is also important to ensure that the terms placebo and placebo effect are only used when discussing unknown variables. This thesis will therefore opt for penetrating and non-penetrating descriptions rather than placebo. As there have been no interventional studies investigating KHA for a pregnancy related condition in the English language, and no studies that have looked at acupuncture efficacy for PPGP in the UK, this thesis looks to address these gaps in knowledge.

Therefore, this thesis aimed to address a number of the deficits in the current published literature surrounding PPGP and its management. An exploration of views held by UK PPGP sufferers, detailed in Chapter 6, lends an original contribution to knowledge of factors surrounding PPGP. Chapter 5 and 7 investigate methods of KHA, which could be used in a large scale, fully powered RCT, indicating feasibility and acceptability of the study protocol and intervention delivery. Chapter 7 also provides data on effectiveness of KHA for PPGP, though these findings are to be interpreted cautiously. The results from Chapter 5 and 7 also provide original contributions to knowledge, outlined in the individual Chapter discussions and overall thesis discussion in Chapter 8.

Therefore, the specific aims for this thesis are:

1. To develop a believable non-penetrating Korean Hand Acupuncture (npKHA) approach
2. To measure acceptability of both npKHA and pKHA through participant retention and adverse events experienced in a non-pregnant, female population
3. To gain an understanding of PPGP as experienced by women in the UK
4. To develop and implement a study investigating the practicalities of delivering KHA for PPGP

The methods and methodology adopted to achieve these aims is discussed in detail in Chapter 4.



## Chapter 4

### Overview of Methodology

#### 4.1 The MRC guideline as a framework

Acupuncture can be considered as a complex intervention, and as such, the Medical Research Council's (MRC) guidance on the development and evaluation of a complex intervention (Craig *et al.* 2006) was sought before embarking upon this thesis. According to Craig *et al.* (2008), the characteristics of a complex intervention are something which has several elements to its delivery, and has a degree of uncertainty about its mechanism of action (Craig *et al.* 2008). As previously discussed in Chapter 3, these characteristics are true for acupuncture and therefore would make the MRC guideline an appropriate framework upon which to base future research.

The MRC put forward a 'development-evaluation-implementation' process (Craig *et al.* 2008), suggesting a complex intervention should be subjected to a number of processes on its journey from development to implementation. These are:

- Development
- Feasibility/piloting
- Evaluation
- Implementation

Although not considered hierarchical, or even cyclical, the framework draws heavily upon the notion that all aspects of this journey are essential to ensure a complex intervention is implemented effectively (Craig *et al.* 2008). This PhD thesis can be seen to take on the process of thorough investigation of KHA in PPGP, thus making its implementation into general physiotherapy practice appropriate. To do this, the author has adopted a mixed methods design underpinned by a Pragmatism philosophy (discussed later within

this Chapter). Quantitative research is the primary method described in Chapter 5 and 7, whereas a qualitative method is the primary approach in Chapter 6. In addition, there are qualitative aspects to Chapter 5 and 7 to help provide additional insight into the quantitative data that was collected. This method is a novel approach to investigating a treatment approach to PPGP in the UK, and is considered as a feasibility study.

Core to the MRC framework for complex interventions is a phased approach to feasibility testing (Craig *et al.* 2008). On a review of pilot and feasibility study reporting, Arain *et al.* (2010) included 54 papers published in four high impact medical journals. They found that the difference between a pilot and a feasibility study is not always clear, with Arain *et al.* (2010) suggesting the characteristics of a feasibility study are most appropriately outlined by the National Institute for Health Research (NIHR) classification. The NIHR (2015) define a feasibility study as a piece of research conducted before a main study, in order to answer the question “Can this study be done?” (NIHR, 2015). Feasibility studies are used to estimate important parameters that are needed to design the main study, and should aim to investigate:

- willingness of participants to be randomised;
- willingness of clinicians to recruit participants;
- number of eligible patients
- characteristics of the proposed outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance rates;
- time needed to collect and analyse data (NIHR, 2015).

Lancaster, Dodd and Williamson (2002) support this definition and recommendation of outcomes a feasibility study should look to achieve, with Arain *et al.* (2010) stating that the purpose of the feasibility study, i.e. to inform a future large scale trial, should be made clear when publishing the article. The MRC framework (Craig *et al.* 2008) highlights that evaluation of complex health interventions are often undermined by poor compliance, delivery of the intervention, recruitment and retention, and smaller than expected sample sizes, all of which can be measured by first adopting a feasibility study. The MRC also stress the importance of highlighting the context in which the complex intervention is conducted to allow for appropriate evaluation and consideration if being implemented in other contexts (Craig *et al.* 2008). All of the above recommendations were considered in the design and execution of this study, with a three phase thesis aiming to provide thorough feasibility testing.

Chapter 6 discusses the development and execution of eight qualitative interviews, which were paramount in gaining a deeper understanding of PPGP. This turned out to be not only enlightening for the author's understanding of PPGP as experienced by UK women, but it produced several unique stand points on the understanding of PPGP, thus lending a considerable amount of originality to the thesis. Along with the literature review in Chapter's 2 and 3, this part of the PhD could be considered to occupy the 'Development Phase' of the MRC framework, providing a sound underpinning for the study in Chapter 7. In addition, it provided some level of stakeholder involvement in the development of KHA outlined in Chapter 7, again something which the MRC framework stipulate as important (Craig *et al.* 2008).

The two primarily quantitative phases are displayed in Chapter 5 and 7. The preliminary study displayed in Chapter 5 explores the opinions of 20 healthy, non-pregnant females

on whether they believed they had received penetrating or non-penetrating KHA. It was delivered in one session and participants were asked to evaluate their belief of what they thought they had received through a Likert type item and open ended questions. This phase was important to the development of the larger study in Chapter 7, as it allowed the author to ensure that both forms of KHA were delivered in a manner which was deemed believable. This was considered important to help strengthen adherence and compliance rates for Chapter 7, which is a parameter that the NIHR (2015) put forward as being important to consider during feasibility testing. From a PhD perspective, this phase created an original contribution to knowledge, as there have been no previous studies investigating the believability of pKHA and npKHA.

The final empirical study, which can be considered to be within the feasibility phase of the MRC framework, is displayed in Chapter 7. This investigation, whereby a non-penetrating and penetrating form of KHA with PPGP sufferers were compared to one another, measured the acceptability and feasibility of conducting a definitive RCT. There is currently no published research that has investigated the use of KHA for PPGP, making this an important contribution to knowledge of how to develop a large scale study investigating KHA, whilst displaying trends on its effectiveness. It reported upon the key parameters considered by the NIHR (2015) for feasibility testing, and thus fits in with the MRC framework approach to developing a complex intervention (Craig *et al.* 2008).

The 'Evaluation' consideration for complex interventions can be seen at the end of each empirical study (Chapter's 5-7), and again as an overarching discussion in Chapter 8. Each discussion highlights the strengths and limitations of each phase individually and collectively, whilst highlighting the original contributions to knowledge. However, as is suggested by Craig *et al.* (2008), Chapter 8 will also suggest implications for a future

larger study into KHA for PPGP, as well as other areas that are requiring closer scrutiny via good quality research.

The 'implementation' consideration will not feature heavily in this thesis, as this will be become more prominent in postdoctoral work, but the author aims to publish aspects of the thesis to allow for dissemination of idea's and research findings. Yet before reporting upon the specific studies conducted as part of this thesis, it is first important to discuss the methods adopted in more detail. The mixed methods approach would seem to be the most appropriate methodology to conform to MRC framework (Craig *et al.* 2008) and NIHR (2015) recommendations, with Pragmatism considered to be a fundamental philosophy, which underpins this type of research (Teddle and Tashakkori, 2009).

## **4.2 Pragmatism**

Pragmatism, as defined by Morgan (2014, p.26), is "a philosophy in which the meaning of actions and beliefs are found in their consequences." In essence, all actions and interactions that a human has, and will ever have, impact upon every subsequent or future decision and experience. Cresswell (2014) puts forward that every experience, no matter how small, will influence a decision made in some way. The more times the individual has a very similar experience producing a very similar outcome, the person develops a sense of predictability of any future outcome, which pragmatists call warranted beliefs (Morgan, 2014). However, pragmatists also believe that these warranted beliefs act only as a very good guess at best, because it is never possible to have an exact experience repeated. Therefore, if the consequences of an experience change, so can the warranted belief (Morgan, 2014). Additionally, pragmatists believe that because no experience can be exactly like another, no two people can have an identical worldview. A world view is how an individual perceives their reality in all its parts, making sense of

their life and others' lives (Teddle and Tashakkori, 2009); in other words, the multiple warranted beliefs an individual has, orientates their overall worldview. However, authors such as Morgan (2014) concede that it is possible for a group of people to have a shared belief surrounding a particular experience, if they have had very similar experiences, or that a multitude of warranted beliefs have led them to similar orientations.

The Pragmatism paradigm is based upon the philosopher John Dewey's explanation of inquiry, which leads to warranted beliefs (Cresswell and Plano Clark, 2011). Morgan (2014) explains that inquiry leads to actions, which requires the individual to continuously reflect on their beliefs. Morgan (2014) suggested a revised theory specifically aimed at how pragmatism can be applied to research: the researcher is continuously reflecting upon the outcomes of their research to consider new research designs which in turn may produce new or better understanding, or perhaps shift the research aim to a different viewpoint, until they arrive at a research design that best suits their question (Morgan, 2014; Cresswell 2014; Cresswell and Plano Clark, 2011).

The pragmatism paradigm quite eloquently suits the process the PhD student goes through to achieve their research goals, as the studentship encourages a research scholarship to culminate in understanding of scientific methods to best apply to healthcare, whilst appreciating the journey and experiences which have led them to that understanding. Put another way, constantly changing warranted beliefs are created as understanding changes, producing an overarching warranted belief on the research process and/or condition being researched. This can then be extended to the likely process that all researchers go through to ensure they arrive at meaningful conclusions to their research, and is perhaps reflective of the MRC framework for complex interventions.

### **4.3 Research paradigms**

A qualitative research paradigm, in its broadest terms, primarily sets out to gain a deeper understanding of a given situation or phenomenon, requiring the researcher to become entrenched within their data, whilst recognising the impact that they as the researcher have upon the data collection and synthesis (Carpenter and Suto, 2008). This explains why in Chapter 2 under '2.3 The symptoms and impact of PPGP', the majority of literature discussed is a qualitative design. Its roots are within an interpretivism philosophy, which considers knowledge to be the product of human interaction and understanding (Saks and Allsop, 2013). The researcher is expected to make comment on how they have interacted with participants and subsequently, how it may have impacted upon the data. Reporting this researcher effect is known as reflexivity (Carpenter and Suto, 2008).

The importance of stating the philosophical and paradigmatic standpoint becomes clear when considering reflexivity, as the viewpoint on knowledge creation will influence how that data is collected, viewed, analysed or reported upon. For example, a pragmatism philosophy underpinning a qualitative paradigm in PPGP has helped to mould the researcher here's views on the condition to give them a deeper understanding of the condition. The researcher here recognises the purpose of doing the research is to create a dialogue with their own current warranted beliefs, and has ultimately reported on findings in Chapter 6 which influence their newly situated warranted beliefs. The researcher here believes that by being exposed to experiences of PPGP, and subsequent analysis of findings from the interviews in Chapter 6, it has helped to influence study conduct in Chapter 7 and conclusions discussed within Chapter 8.

One form of qualitative research is the heuristic approach, which emphasises the researcher's warranted beliefs by requiring the researcher and participant to have a very

similar issue at heart (very similar shared views), for example both to have PPGP. The data is produced in equal manner from researcher and participant, and both learn about the condition through this research partnership. Moustakas (1990) puts forward that the heuristic approach can help produce an understanding not only for the researcher themselves, but to help and try understand the issues suffered with others through empathy. The heuristic approach is perhaps the most distant methodology/paradigm from quantitative research, which demands that the researcher is objective and has minimal impact on data collection and analysis. Interestingly, no studies were found adopting a heuristic research approach for PPGP. Although this does not detract from the quality of evidence put forward, it is slightly surprising given that most studies discussed in Chapter 2 were published in countries of high incidence rates of PPGP, and that the primary authors were women.

The heuristic method could be situated within pragmatism, as it could help researchers understand their own warranted beliefs, and how they may be impacting upon the data collection and extraction, however clearly cannot be an approach adopted by this PhD student researcher as they will never experience PPGP. However, using a purely qualitative approach, being inductive and to produce a theory that was specific to those that were involved within the study, could not be reasonably used to investigate a potential beneficial treatment for PPGP. A weakness of the qualitative paradigm is that it often focuses upon very small groups and therefore should be treated with caution when generalising (Saks and Allsop, 2013).

A purely deductive methodology, primarily using quantitative methods, aims to generalise any data produced, whilst keeping the research process as objective as possible. A



positivism philosophy, whereby fact is derived from systematically observing and measuring a phenomena, is one that is most often associated with quantitative research, and therefore aims to look at specific variables to investigate cause and effect relationships (Creswell and Plano Clark, 2011). It is the preferred approach to investigating the effectiveness of a given treatment, as it allows the researcher to identify whether the intervention impacts upon an outcome, or if a particular variable is responsible for a given response. To do this the researcher adopts a reductionist approach, whereby they look to investigate whether an independent variable (for example, the treatment) is the cause of a change to an outcome measure by adopting inclusion criteria to their sample. Examples of this approach can be seen within Chapter 3, under '3.6 acupuncture for PPGP' (page 48), whereby researchers investigate the effect acupuncture has upon PPGP.

The limitations to this approach by itself, from a research training perspective, is that it encourages the researcher to distance themselves from the research participants in order to reduce researcher influence on the results, and to reduce any potential uncontrolled variables from influencing the data produced. Whilst this helps to keep the results 'clean', it means that the researcher is not as close to the people producing that data, and therefore it does not allow for a deeper understanding of a condition, such as PPGP. This could mean that small but significant effects of a treatment, say reported by a participant as a comment rather than through an outcome measure, could be missed and therefore not reported upon. Ekdahl and Petersson (2010) and Smith and Crowther (2002) provide evidence of this, as they provide qualitative data to support their quantitative findings, providing a deeper understanding of why the quantitative findings were found. Therefore, if the researcher was to combine the quantitative and qualitative forms of data, it could lead to a deeper understanding of PPGP whilst producing evidence on a given treatment modality.

Mixed methods research (MMR), although advocated by authors as early as the 1970's, is a relatively new method/methodology that has only in the last 10 years become an established approach to scientific investigation (Creswell and Plano Clark, 2011). Both quantitative and qualitative data are valued equally, and pragmatism is most frequently adopted as a philosophical standpoint due to it being inclusive of all types of knowledge generation. Creswell and Plano Clark (2011) put forward that mixed methods "provides the most complete analysis of problems", due to the limitations that analysing numbers or words independently of each other provides. Teddlie and Tashakkori (2009) argue that MMR was born from literature on triangulation, where researchers looked to validate findings using different methods of inquiry. Creswell and Plano Clark (2011) highlight the issues with providing an exact definition of what MMR is, demonstrating that its definition has changed over recent years to incorporate different viewpoints on what it entails.

They instead suggest some core characteristics of MMR, which include:

- collecting and analysing qualitative and quantitative research
- merges and integrates qualitative and quantitative data, which inform one another
- priority given to one or both forms of data
- use in a single or multi-phase study
- framed within a philosophical worldview
- research designed to allow for a logical study plan

(Creswell and Plano Clark, 2011)

Teddlie and Tashakkori (2011) put forward two broad approaches to MMR. The parallel form is where two types of data are collected and analysed together, and the sequential form is where one type of data provides a basis for collection of another type of data.

Cresswell and Plano Clark (2011) went further by considering when and where the mixing occurs in the research process, such as an embedded model where quantitative and qualitative data are utilised simultaneously. Teddlie and Tashakkori (2011) made the distinction between mixed methods and mixed model designs, stating that mixed methods is the most appropriate terminology for mixing of methods in one study, whereas the mixed model design is more apparent when looking at a larger programme of research (Cameron, 2009). Teddlie and Tashakkori (2011) also put forward MMR as a cyclical approach to research, promoting reevaluation of findings, supporting findings from different paradigms, and suggestions for future research to further understanding of a given topic. This not only resonates closely with the MRC framework for complex interventions (Craig *et al.* 2008), but also with the process of the PhD scholarship.

Although identifying a philosophical stand point is mostly associated with qualitative research, the researcher here feels that it is still important for researchers to identify their philosophy, or perhaps more specifically their paradigmatic view, that may have had an influence on the reporting of results. Cameron (2009) explained that the pragmatist viewpoint is that it is a 'false dichotomy' when it comes to the division of purely quantitative or qualitative viewpoints to knowledge acquisition, and thus advocate the appropriate use of both methods. The statement by Johnson, Onwuegbuzie and Turner (2007) that pragmatism is the 'primary philosophy of mixed research' is echoed by Cameron (2009) who believe it to have a 'strong philosophical foothold' within MMR. Further support is demonstrated in a review by Tashakkori and Teddlie (2003), who found at least 13 different authors considering pragmatism as the most appropriate paradigm or philosophy to explain their worldview when conducting MMR. This extends to CAM research, with Bishop and Holmes (2013) promoting the use of pragmatism as an overarching paradigm, as it al-

allows the qualitative work to be considered in light of how it can engage and respect a patient, whilst allowing the quantitative work to put forward arguments for changes to practice or funding for an intervention. The use of pragmatism is viewed by the researcher here as the most appropriate paradigm to underpin MMR, as it encourages the fusion of positivism and interpretivism to create a worldview. The use of pragmatism and MMR has, however, not been without controversy.

One such issue with MMR, highlighted by Creswell (2014), is that of a paradigm eclecticism. The 'purists', such as Howe (2004), felt that paradigms have distinctions between them that prevent any kind of merging whatsoever, because of the philosophical assumptions that a paradigm is attached to Howe (2004). This prevents quantitative data being merged with qualitative data, because the philosophy of quantitative data is that only phenomena that can be measured exist, whereas qualitative philosophy dictates that fact is derived from the limit of human interaction with the world (Creswell, 2014). It is clear that this line of thought also leads to a dismissive consideration of pragmatism. However, pragmatism prevails as it allows the most appropriate method to answer a given question (Teddlie and Tashakkori, 2009), providing no prejudice to positivism or interpretivism. This is sometimes seen by critics as a 'do what you like' approach, yet it encourages the researcher to select the most appropriate method to answer the question, not force inquiry through an interpretation of knowledge generation (Morgan, 2014).

Critics such as Howe (2004) point to MMR as undermining the importance of qualitative work, relegating it to a supporting role of the larger quantitative study. Further to this, Giddings (2006) extended Howe's (2004) views as they suggest that the terminology being used in MMR was paying lip service to, and not truly identifying with, the core principles of qualitative phases when considering philosophical standpoints. Johnson,

Onwuegbuzie and Turner (2009) also highlight this issue, questioning whether quantitative or qualitative methodology (or neither) should dominate an MMR methodology. These arguments lend weight to the purist view that MMR is incompatible because competing philosophies cannot co-exist within one context.

Lewin, Glenton and Oxman (2009) performed a methodological study reviewing the use of qualitative methods alongside RCT's for complex healthcare interventions. They focused upon methods where qualitative research was used to support or explain an RCT. Of the one hundred RCT studies that were extracted from a literature search, thirty used qualitative data, with twenty three studies using qualitative data collection and analysis techniques. The authors report that this number is lower than they would expect, given the increase in belief that qualitative work could enhance results of RCT's, and more so that when contacting the authors of these studies, they valued the results of any qualitative literature (Lewin, Glenton and Oxman, 2009). Most of the studies included utilised qualitative methods prior to the RCT, suggesting the sequential approach the most prevalent. The authors also highlight the quality of reporting for the qualitative phases were poor. The researcher here feels that this portrays a view that qualitative data needs only superficial mention and supports the views of Howe (2004) and Giddings (2006) that qualitative research is not been given appropriate emphasis. Finally, Lewin, Glenton and Oxman (2009) highlight that further mixing of methods and methodology would enhance reporting and understanding of a given condition, although Johnson, Onwuegbuzie and Turner, (2009) are unsure if there is a best time for this mixing to occur.

#### **4.4 Use of MMR in acupuncture**

Verhoef *et al.* (2005) discussed treatments, such as acupuncture, that deal with 'whole systems', a concept that considers the whole effect a treatment may have as opposed to

very specific effects to one area of the body. They advocate the MMR approach due to the inadequacies of pure quantitative approaches being reductionist in nature, therefore not being able to assess treatment effects in total (Verhoef *et al.* 2005). They continued by stating that when using MMR, it can help to address the complex nature of a given condition. However, Verhoef *et al.* (2005) did not stipulate which form of MMR is best suited, though embedded and sequential approaches appear to be the main suggestions. In particular, they put forward that researchers can consider using qualitative methods to find if outcomes are meaningful to the participant, and what the meaning of an intervention is to the recipient. In addition, Verhoef *et al.* (2005) indirectly advocates the MRC framework for complex interventions because it enforces the researcher to think of a programme of research as opposed to a one off study, and to consider the use of a range of methodologies.

Bishop and Holmes (2013) conducted a systematic review of mixed method approaches to CAM research, focusing upon papers that had been published in 2012 in the top 10 CAM journals. They used the Mixed Methods Appraisal Tool (MMAT) and included 80 studies, nine of which had chosen to publish phases of their work separately (Bishop and Holmes, 2013). Bishop and Holmes (2013) put forward that the traditional RCT approach to investigation does not properly assess outcome of CAM as they are considered multi-factorial, complex interventions and the underlying mechanisms of how they work are still being researched. Bishop and Holmes (2013) state that mixed method approaches complement the strengths of both the qualitative and quantitative aspects of research, and the authors gave higher regard to those studies that explicitly identify or resolve the philosophical challenges associated with MMR. Despite the call for further mixed methods work, Bishop and Holmes (2013) identify that research in CAM is still overwhelming dominated by quantitative approaches, accounting for 84% of published

articles in the top ten CAM journal as opposed to 4% MMR. Their findings on quality appraisal of the MMR studies were that the quantitative elements benefitted from higher quality in reporting than the qualitative sections, perhaps confirming the fears of Howe (2004) and Giddings (2006), and in support of another review of MMR in health services research (O'Cathain, Murphy and Nicholl, 2008). In addition, the philosophical tensions within MMR were not addressed by any of the included 80 studies, which Bishop and Holmes (2013) stated should have been done (they themselves putting forward a pragmatism philosophy).

Included in the Bishop and Holmes (2013) review was White *et al.* (2012), who utilised a mixed methods approach to investigate the impacting factors upon effect within an acupuncture treatment. The method adopted appears to be an embedded approach as participants were asked to complete outcome measures (quantitative data) and immediately follow up their completion with semi-structured interviews. Quantitative data was reported, with White *et al.* (2012) displaying the qualitative aspect through a basic thematic analysis, producing three themes. They state that the qualitative aspect is the subservient method, acting primarily to support and provide deeper understanding of the quantitative data, something which Lewin, Glenton and Oxman (2009) would consider appropriate. An additional strength to their reporting is that within the results section, they integrate both forms of data, though always with the quantitative data as the primary focus. However, as highlighted as a trend by Bishop and Holmes (2013), reporting of reflexivity and philosophical stand points are absent, and is continued to be observed in other CAM publications.

A paper by Reid and Alfred (2013) also used an MMR approach to investigate coping

strategies with women who sought TCM for infertility. They adopted an embedded approach, involving a semi-structured interview immediately followed by two paper-based questionnaires to complete. As with White *et al.* (2012), no attempt was made to provide reflexivity and no debate was given around the philosophical underpinning. Their description of data analysis was extremely basic for the qualitative phase, and as it is presented, would seem that important steps within the thematic analysis process were missed. This was mirrored in the quantitative description, and followed by no critique within the discussion of the MMR approach, something which should be done considering its controversial standing with research methodology discussions (Cameron, 2009; Bishop and Holmes, 2013). This suggests that when reporting upon MMR, the precious amenity of space limits how much methods and data analysis can take up. It may reflect editorial restraints as opposed to author ignorance, which is coupled with the fact that most journals do not offer guidance on how to submit MMR. However, the results and discussion of Reid and Alfred (2013) is integrated, with neither method of data collection clearly favoured over another, lending credibility to the editorial argument.

Bishop *et al.* (2011) adopted a sequential exploratory, mixed methods design to investigate how patients choose their acupuncturist, using a qualitative method of semi-structured interviews followed by a quantitative factorial design. They stated a Pragmatic philosophical paradigm without giving any further details as to what pragmatism is or why it was chosen, yet this is a strength rarely observed in MMR in CAM. However, there was no reporting of reflexivity, an integral part of qualitative research to understand how the data collection and analysis may have been influenced (Carpenter and Suto, 2008). The qualitative phase outlined the participant numbers, types of questions asked and briefly how the data was analysed, adopting thematic analysis. The quantitative phase used a factorial method, asking participants which acupuncturist they would most likely seek



treatment with from a pre-set list, partially derived from the qualitative phase. The quality of this study is enhanced through a combined results display of both qualitative and quantitative phases, producing an integrated discussion around the topic, as is suggested to be done by Cameron (2009). This demonstrates that the authors consider each method to be of equal footing in terms of meaning, and thus champions MMR as a way to successfully integrate quantitative and qualitative strengths.

Finally, one study that adopted MMR for acupuncture and PPGP is Ekdahl and Petersson (2010), and was discussed earlier in Chapter 3. This study primarily adopted a quantitative focus, although they do expand upon what their themes were, and provided these findings in conjunction with their VAS and SF-MPQ scores to give an explanation for their results. This demonstrated that not only is MMR an appropriate method for acupuncture research, but also is important to consider using in the area of PPGP. Although this lends support for the mixed method approach adopted in Chapter 7, Ekdahl and Petersson, (2010) fail to discuss the philosophical underpinning to their research, which undermines the qualitative element of the MMR approach. In addition, as stated by Bishop and Holmes, (2013), authors should put forward a discussion surrounding the use of the MMR approach, which Ekdahl and Petersson, (2010) do not do. As this thesis has discussed the underpinning rationale and philosophy that underpins it, it is considered by the researcher here that the MMR research conducted for this PhD can be compared favourably to the existing literature.

#### **4.5 Implementation of MMR for this thesis**

As outlined in Chapter 2, KHA can be considered complex and thus guided by the MRC framework for complex interventions (Craig *et al.* 2008). The guideline champions the use of methods which look to assess whether an intervention works in everyday practice,

something which resonates closely with pragmatism philosophy. Craig *et al.* (2008) also advocate the use of evidence from a variety of sources that do not share the same weaknesses (Craig *et al.* 2008). By combining deductive and inductive approaches through pragmatism and MMR, the researcher here could better understand the condition of PPGP through interviews outlined in Chapter 6, and then use this warranted belief on PPGP to help develop the study outlined in Chapter 7. This would provide the important, fundamental ground work to underpin any larger study aimed at investigating the effectiveness of KHA for PPGP. By adopting recommendations from the MRC framework into the research design, it enhances the possibility of the research being funded to allow for a definitive RCT, and follows accepted guidelines in which to develop a complex intervention.

#### **4.6 Chapter summary**

Although conducting a purely qualitative piece of research would deepen the researcher's understanding of the condition, by focusing primarily on the qualitative design would have meant not being able to investigate a potential intervention for PPGP (although admittedly, this could have been conducted post-PhD). As with the more deductive, quantitative approach, the researcher here felt his scholarship and breadth of understanding of the research process could be somewhat hindered. From a Pragmatist view point, by combining quantitative and qualitative methods, it not only enhances understanding for the individual but also produces something tangible that health care professionals could use in their clinic. The MMR approach is advocated by Bishop and Holmes, (2013) and Verhoef *et al.* (2005) as an appropriate method for acupuncture research, and aligns well with the MRC framework for complex interventions. In addition, by adopting an MMR approach, it will produce a level of originality to this thesis, as no MMR studies have been published in the UK investigating PPGP, with it being the first to

openly utilise pragmatism as its philosophical underpinning. In doing so, it will address the issues raised in this chapter surrounding MMR quality of reporting. To begin this feasibility study, an investigation in to the believability of pKHA and npKHA will be presented, adopting both quantitative and qualitative forms of data to inform the study presented in Chapter 7.

## **Chapter 5**

### **Development of an Intervention Protocol for Korean Hand**

#### **Acupuncture**

##### **5.1 Introduction to Chapter**

Within the RCT, there are at least two groups compared to one another, aiming to decipher whether one or more variables have had an impact on outcome (Bowling and Ebrahim, 2005). To do this, the researcher must attempt to control for all potential variables, other than the independent variable(s) that is under investigation. In doing so, the researcher improves the internal validity of the study and therefore can be confident that findings obtained are as a result of the independent variable (Bowling and Ebrahim, 2005). When considering a complex intervention such as KHA, the potential known variables are numerous and are discussed in depth in Chapter 3. In order for the researcher to ascertain whether the act of penetrating the skin has had an impact upon an outcome, for example pain, the study design should compare the intervention, in this case pKHA, to another group, npKHA. As this has not been conducted previously, the study outlined in the method section for this chapter provides an original contribution to knowledge whilst helping to inform the intervention protocol outlined in Chapter 7.

Placebo controlled trials are necessary to ensure an experiment is not only controlled for in variables such as the Hawthorn effect and treatment expectancy, but to also advance knowledge on whether factors such as penetrating needling are the most important part of an acupuncture treatment session. As previously discussed in Chapter 3, in order to do this, it is necessary to first establish a protocol for KHA, which will culminate in an original contribution to knowledge surrounding acupuncture delivery, as there is currently no non-penetrating acupuncture approach that has been investigated for use solely on

the hand. As stated in Chapter 4, the MRC framework for complex interventions recommend that the prospective researcher systematically develops the intervention prior to its evaluation (Craig *et al.* 2008). The importance of investigating the acceptability and credibility of an intervention is one of the many precursors to the development and appropriate execution of an RCT (Lancaster *et al.* 2002), and so it was considered important to first investigate believability of the intervention before being introduced into a larger study. As will be discussed below, several authors have investigated body acupuncture protocols prior to their inclusion within larger studies, primarily focusing upon the believability of penetrating and non-penetrating forms of acupuncture.

## **5.2 Measurement of Believability**

In a systematic review by Zhang *et al.* (2015), the authors reviewed papers that adopted one of three sham acupuncture devices (all of which were non-penetrating). The authors concluded that these devices did not provide adequate blinding, and therefore further research is needed to provide a more credible approach. Outlined below are a number of non-penetrating approaches to acupuncture.

An exploratory trial by Takakura and Yajima (2007) investigated whether both the practitioner and patient could be blinded when receiving penetrating or non-penetrating needles. Sixty participants and ten acupuncturists were asked to rate whether they felt the needle had been penetrating or non-penetrating, with the researchers having developed a needle that prevented the practitioner and patient from seeing the needle being inserted. Takakura and Yajima (2007) found that both practitioners and participants were unable to distinguish whether they had received (or administered) a penetrating or non-penetrating needle. Takakura and Yajima (2007) concluded that because of the indistinguishability, this needle could be utilised in larger scale RCT's which aim to compare

penetrating to non-penetrating acupuncture. However, although this supports the believability of a non-penetrating approach to acupuncture, this type of needle has a prohibitive cost (£1.75 per needle compared to £3.42 per one hundred standard needles), and clinical anecdotal evidence would suggest potential for unblinding if the needles were to fall off (which is more likely when applied to the bony/tendinous dorsum of the hand). In addition, Zhang *et al.* (2015) put forward that more research is needed in clinical populations to ascertain its reliability.

Tough *et al.* (2009) compared penetrating and non-penetrating versions of acupuncture within a whiplash suffering population. The non-penetrating needle was an acupuncture needle that had been blunted using 'specialist cutting equipment' (Tough *et al.* 2009), with individuals randomised to either the penetrating or non-penetrating group. They received the intervention in between two to six sessions, with needles seemingly located at the cervical spine area. They measured treatment belief by asking participants to mark on a form whether they felt they had had: penetrating acupuncture, non-penetrating acupuncture or were uncertain. Of the 41 individuals who were recruited, 20 were in the penetrating and 21 were in the non-penetrating group, with findings indicating that belief of receiving acupuncture was similar between the two groups ( $p = >0.2$ ). Although these findings indicate a non-penetrating approach is as believable as a penetrating approach to acupuncture, the cost of blunting the needles was prohibitive for this PhD, and was considered an unnecessary methodological step when considering work by Sherman *et al.* (2002).

Sherman *et al.* (2002) adopted a non-penetrating approach in their two phase cross over design. First, ten healthy individuals were given penetrating and non-penetrating acupuncture, primarily over acupoints on their lower back. The researchers used a toothpick

to prick the skin for the non-penetrating approach, which attempted to mimic penetrating acupuncture, and standard acupuncture needles inserted to the correct depth in the penetrating group. The participants were then asked to complete a Likert type item scale, which ranged from 'definitely real needle' to 'definitely imitation needle'. Sherman *et al.* (2002) found that the non-penetrating toothpick approach was considered believable, with it being considered slightly more realistic than the penetrating form.

These findings demonstrated that the penetrating and non-penetrating acupuncture methods could be used in a future study, and was subsequently adopted in a large scale RCT investigating acupuncture for CLBP (Cherkin *et al.* 2009). However, despite Sherman *et al.* (2002) demonstrating a believable non-penetrating acupuncture approach for CLBP, and one which is more likely than the Takakura and Yajima (2007) double-blinded needle to be appropriate to use on the dorsum of the hand, further investigation was warranted to assess believability when applied as a mimic KHA approach. This form of non-penetrating acupuncture was not included in the Zhang *et al.* (2015) review, presumably because the intervention did not constitute being a device. The approach that was adopted for the non-penetrating KHA group in this chapter was the use of a toothpick to simulate the initial pricking sensation of needling. In addition, there is currently no non-penetrating acupuncture approach that has been attempted to be investigated for use solely on the hand, an area of the body which is much more sensitive than the lower back, lending originality to this phase of the thesis.

### **5.3 Outcome measures for Distinguishability and Credibility**

Likert type items are a scale of five to seven points whereby the recipient rates their perception of what they have received to a statement that most closely represents their opinion (Field, 2009). However, Carifio and Perla (2007) have put forward that the use of

a single Likert type item is prone to fluctuating responses, reducing its rigour. That said, in the absence of a validated outcome measure, Sherman *et al.* (2002), who looked to validate a non-penetrating acupuncture approach, adopted a five point Likert type item ranging from 'Definitely real acupuncture needles' to 'Definitely not real acupuncture needles' when asking participants in their penetrating versus non-penetrating acupuncture cross over study. However other authors such, as Tough *et al.* (2009), have opted for a simpler "what treatment do you think you received" question, though this seems to be the only acupuncture study to have done this.

For the study outlined in this chapter, the outcome measure adopted included a Likert type item that ranged from 'definitely received penetrating KHA' to 'definitely did not receive penetrating KHA'. This was followed by an open ended question 'Why do you think you have/have not received Korean Hand Acupuncture?', to identify if there were any factors that could blind/unblind the participant to the group they had been allocated to (see Appendix 3). Smith and Crowther (2002) asked participants why they thought they had received acupuncture, and provided insight into what factors may influence an individual's belief. In addition, Bishop and Lewith (2008) reported that needle sensation was a large factor influencing people's beliefs on if they have received penetrating acupuncture. By adopting a mixed methods approach, it was the intention that more in-depth data would be gained than would have been through a pure qualitative or quantitative study, whilst remaining comparable to previous studies of penetrating versus non-penetrating believability such as Sherman *et al.* (2002). The results were then taken into consideration for the execution of the feasibility study in Chapter 7, with potential influencing factors of believability attempted to be controlled for in the study design.



#### **5.4 Sampling in previous acupuncture distinguishability studies**

There were no studies found that looked at female only participants when assessing believability of a penetrating and non-penetrating form of acupuncture, though a number of women from mixed sex samples were extrapolated from existing research to help inform the sample for this study. Kleinhenz *et al.* (1999) discussed a 7 participant pilot study (not published) before embarking on their subsequent randomised clinical trial. Tough *et al.* (2009) provided no details on the demographics of the 41 participants in their study, making it impossible to ascertain how many were female. White *et al.* (2003) investigated whether a non-penetrating needle was credible and included 37 participants, 23 of who were female. Takakura and Yajima (2007) had a total of 60 participants, 25 of whom were female. In contrast, Sherman *et al.* (2002) included 10 participants in their initial study (5 being female).

#### **5.5 Aims**

The aims of this phase were to:

- To develop a believable npKHA approach
- To measure acceptability of both npKHA and pKHA through participant retention and adverse events experienced in a non-pregnant, female population

#### **5.6 Hypothesis**

There will be a statistically significant difference between the pKHA and npKHA groups for belief of what intervention was received at initial and final opinion

#### **5.7 Null Hypothesis**

There will be no statistically significant difference between the pKHA and npKHA groups for belief of what intervention was received at initial and final opinion

## **5.8 Methods**

### **5.8.1 Ethical approval**

Ethical approval was gained via Northumbria University ethics panel (Reference number RE-HLS-12-130701-51d1815248c3f) on 7th August 2013. Data collection began on 21st August 2013, and was completed on 4th October 2013.

### **5.8.2 Study design**

A two group, between and within subjects design to measure the believability of a novel npKHA approach was adopted. Sherman *et al.* (2002) used a cross over design to determine the credibility of the acupuncture placebo approach. However, as the inclusion criteria of the feasibility study reported upon in Chapter 7 would be to only include acupuncture naive individuals, the researcher here considered the cross over design unnecessary.

### **5.8.3 Sample**

The sample size selected was based upon the few similar conducted studies, with White *et al.* (2003) and Takakura and Yajima (2007) including more than 20 women, Sherman *et al.* (2002) only 5, making an average of 18 women per believability study. It was therefore considered that aiming to recruit 20 participants, ten in each group, would be adequate to provide information on the believability of the non-penetrating intervention and allow for a 10% drop out rate. The population was recruited using a convenience sampling method, as they were students from Northumbria University.

#### **5.8.4 Inclusion criteria**

Healthy adult women, who were:

- Not pregnant (as was included in Sherman *et al.* (2002))
- Between 18-40 years of age (the population investigated in the feasibility study)
- Were not taking medication
- Had not had acupuncture in the past (as was included in Sherman *et al.* (2002))
- Were not allergic to metal/Elastoplast
- Were not contraindicated to acupuncture

#### **5.8.5 Blinding**

Participants were blinded to pKHA and npKHA via blindfold goggles. Participants were given individual time slots to prevent any contact between subjects. The Chief Investigator (CI) administered the KHA for both groups, collected all outcome measures and analysed the data for all participants. Evidence of believability was assessed through the Likert type item and supplementary questions upon which intervention the individual thought they had received (see Appendix 3). Potential unblinding was also measured at one week post intervention using the same outcome measures.

#### **5.8.6 Recruitment**

Participants were recruited via email through the Northumbria University email system, which contained an attached participant information sheet (PIS) (Appendix 4); individuals were asked to confirm their interest by replying via email. On attending, the participants were asked to provide signed consent (Appendix 5) and then complete the demographics form (Appendix 6).

### **5.8.7 Randomisation**

A simple randomisation process of opaque envelopes, with either code 5 or 6 written on a card inside, was used. The participant on arrival, and after consenting to be involved in the trial, picked an envelope, of which there were 20 in total, ten indicating pKHA (5), ten indicating npKHA (6). After the envelope had been chosen, it was discarded.

### **5.8.8 Outcome measure (Appendix 3)**

Demographic data, displayed in Table 4, was collected at the initial assessment and reflected the demographics collected in the feasibility study outlined in Chapter 7. Based upon Sherman *et al.* (2002), the outcome measure within this study included a Likert type item that ranged from 'definitely received penetrating KHA' to 'definitely did not receive penetrating KHA'. This was followed by an open ended question 'Why do you think you have/have not received Korean Hand Acupuncture?', to identify if there were any factors that could blind/unblind the participant to the group they had been allocated to (see Appendix 3). This was completed immediately after the KHA session of 30 minutes, and again one week post penetrating/non-penetrating KHA session. This one week re-measurement was completed via email.

### **5.8.9 Procedure**

For this study, both procedures, toothpick and needling, replicated common practice of how KHA is delivered, with the protocol used following that of Sherman *et al.* (2002). The CI gave the same explanation to both groups of what to expect, to try and control for the investigator's input being an influencing factor. The npKHA procedure involved participants in long sitting on a treatment plinth, with blindfold goggles placed upon them by the CI and confirmation given that the participant was unable to see.

The CI held the skin taut around each KHA point (as per standard practice) and placed a standard KHA needle guide tube containing a toothpick against the skin. The CI then tapped the toothpick, and then quickly withdrew both the toothpick and guide tube (see Appendix 7 for location). The participant remained on the plinth for 30 minutes to simulate the period that KHA needles are typically left in situ. Finally, to simulate withdrawal of the needle, the researcher stretched the skin around each KHA point tightly; pressed a cotton ball firmly on the stretched skin, then touched the skin with a toothpick (without a guide tube) momentarily, and finally pulled the toothpick away quickly using the same hand movements as in regular needle withdrawal. A sticky plaster was placed over the area of pricking which the participant was asked to keep in situ for 24 hours. The participant completed the believability outcome measure (Appendix 3) immediately after the 30 minute session, and repeated the outcome measure one week later via e mail.

The pKHA group had the same procedure, only the needles replaced the toothpick, with the needles staying in situ for 30 minutes. The introduction of the sticky plaster over areas that had received npKHA/pKHA was an attempt to prevent from un-blinding the penetrating group; it was considered possible by the CI that the pKHA group could realise that needles had been inserted if needle marks were observed.

#### **5.8.10 Data analysis**

Inferential and descriptive statistics were used to analyse the general demographic data between the two groups. This data analysis was conducted to report upon homogeneity of the study. If baseline homogeneity was not achieved, the heterogeneous characteristic could be the cause of any differences observed. This would then produce uncertainty as to whether the believability of the KHA approach was due to the intervention adopted or due to a demographic characteristic. A Kolmogorov-Smirnov test was conducted on

the appropriate demographic data before deciding on whether to perform a parametric or non-parametric test. A Mann Whitney U test, with a two tailed Exact significance test was used for all non-parametric data, and an independent samples t-test was performed on the parametric data.

For the quantitative data produced from the believability outcome measure, within group analysis was via a Wilcoxon Signed Rank Test, and between group analysis was performed through the Mann Whitney U test, both of which were interpreted via the two tailed Exact test. All quantitative data was analysed through the software SPSS for windows version 22. The qualitative data collected from the open ended question was analysed using a content analysis approach, more specifically a manifest content analysis, as the description of the visible, obvious components of the text provided by participants are presented in the results (Graneheim and Lundman, 2003). Although the manifest approach provides only surface analysis, the data collected from the open ended question was unlikely to be in-depth. The raw data collected from the open ended question is displayed in Appendix 8, with a summary of findings displayed as themes in the results section below. The results of the manifest content analysis were used in methodological design considerations for the study reported upon in Chapter 7.

#### **5.8.11 Recording of adverse events**

Adverse events were recorded using the table set out in Appendix 2. Within the PIS (Appendix 4), the potential adverse events were outlined. Each participant was asked verbally whether they had experienced any side effects/adverse events, either listed on the PIS or otherwise, on the initial session, and again via written email for the subsequent one week post intervention outcome measure.

## **5.9 Results**

### **5.9.1 Adverse events**

No adverse events were reported.

### **5.9.2 Study attrition**

This study suffered no dropouts, with each participant completing the outcome measures at initial opinion and final opinion in full. Twenty women were recruited, ten to each group, over a period of six weeks.

### **5.9.3 General demographics**

As outlined in Table 4, demographics for marital status ( $df=20$ ,  $z= N/A$ ,  $p=1$ ) was constant across both groups, as all students were single. Education ( $df=20$ ,  $z=0.487$ ,  $p=0.481$ ) and hours of exercise per week ( $df=20$ ,  $t= 0.163$ ,  $p= 0.816$ ). show that the groups were homogenous for these variables. However, there was a significant difference in age between the groups ( $df=20$ ,  $z=0.262$ ,  $p=0.05$ ), although the npKHA group had a median of 22 over the median of the pKHA group at 20.

**Table 4: Participant demographic data**

<b>Demographic</b>	<b>Age in years</b>	<b>Marital Status (single or married)</b>	<b>Education (highest qualification)</b>	<b>Hours of exercise per week</b>
<b>Normality test*</b>	0.001	N/A	N/A	0.174
<b>Test statistic</b>	-2.823	N/A	0.487	0.163
<b>df</b>	20	20	20	18
<b>IQR</b>	19-26	Single	NA	3-12
<b>npKHA (median/mean)</b>	22	All single	(n=7) A levels	6.7
<b>pKHA (median/mean)</b>	20	All single	(n=9) A levels	6.4
<b>Statistical test</b>	Mann Whitney U	Mann Whitney U	Mann Whitney U	Independent t - test
<b>Statistical Sign. (p=0.05)</b>	p= 0.002	p=1	p=0.481	p=0.816

\* Kolmogorov-Smirnov

#### **5.9.4 Initial opinion of intervention received**

Table 5 displays the initial opinion of participants, provided immediately after receiving the intervention. For the npKHA group, one person felt they definitely had pKHA, four reported that they probably had pKHA, three were uncertain and one stated that they probably did not have pKHA. At the initial opinion for the pKHA group, three felt they definitely had pKHA, six stated that they probably had pKHA and one was unsure; no women felt they probably or definitely did not have pKHA. The most common statement was 'probably pKHA' for both groups, with the median in the npKHA group between



‘probably pKHA’ and ‘uncertain’ and the pKHA group median being ‘probably pKHA’.

**Table 5: Initial opinion of intervention received**

	n	Definitely pKHA	Probably pKHA	Uncertain	Probably not pKHA	Definitely not pKHA	Median	IQR
<b>npKHA group</b>	10	1	4	3	1	1	2.5 (between probably pKHA and un- certain)	1-5
<b>pKHA group</b>	10	3	6	1	0	0	2 (Probably pKHA)	1-3
<b>Total</b>	20	4	10	4	1	1		

### 5.9.5 Opinion of intervention after one week

Table 6 displays three women in the npKHA group believed they definitely had pKHA and two women in each category for; probably had pKHA; uncertain; and probably did not have pKHA. One woman felt they definitely did not have pKHA. In the pKHA group, one felt they had definitely had pKHA, seven felt they probably had pKHA, one was uncertain and one reported that they probably did not have pKHA, with no one stating they definitely did not have pKHA. The most common statement in the npKHA group was ‘definitely pKHA’, and in the pKHA it was ‘probably pKHA’. The most common statement was ‘probably pKHA’ for both groups, with the median in the npKHA group between ‘probably pKHA’ and ‘uncertain’ and the pKHA group median being ‘probably pKHA’.

**Table 6: Opinion of intervention after one week**

	n	Definitely pKHA	Probably pKHA	Uncertain	Probably not pKHA	Definitely not pKHA	Median	IQR
npKHA group	10	3	2	2	2	1	2.5 (between Probably pKHA and uncertain)	1-5
pKHA group	10	1	7	1	1	0	2 (Probably pKHA)	1-4
Total	20	4	9	3	3	1		

#### 5.9.6 Within group comparisons

Table 7 demonstrates the Wilcoxon signed test for within group comparisons revealing that within the npKHA group, the opinion on if they had received pKHA largely remained very similar at initial and one week ( $p=1$ ). The pKHA group also registered a non-significant difference ( $p=0.125$ ).

**Table 7: Opinion at initial and final: within group comparisons**

	Z value	df	Statistical significance (Wilcoxon signed Ranks test)	Null hypothesis retained?	Outcome
npKHA	-0.108	10	$p=1$	Yes	opinion of intervention remained unchanged from initial to final opinion
pKHA	-2.000	10	$p=0.125$	Yes	opinion of intervention remained unchanged from initial to final opinion

### 5.9.7 Between group comparisons

Table 8 displays between group statistical differences were non-significant at both the initial opinion ( $p=0.077$ ) and opinion at one week ( $p=0.643$ ), with the level of agreement between the groups becoming stronger at the final opinion point. This confirms the null hypothesis that there will be no statistically significant difference between the pKHA and npKHA groups for belief of what intervention was received at initial and final opinion.

**Table 8 - Between group comparisons for initial and final opinion**

	Z value	df	Statistical significance (two tailed Mann Whitney U test)	Null hypothesis retained?	Outcome
<b>Initial opinion</b>	-1.955	20	$p=0.077$	Yes	Opinion of intervention was the same between the two groups
<b>Final opinion</b>	-0.519	20	$p=0.643$	Yes	Opinion of intervention was the same between the two groups

### 5.9.8 Emerging themes from believability qualitative comments

All qualitative data, from both initial opinion and final opinion produced from the question "Why do you think you have/have not received penetrating KHA?" can be found in Appendix 8. Five emerging themes that appeared to influence participants' belief on whether they had received pKHA or not were:

- Local needle sensation (recorded 12 times)
- Non needle sensations (recorded 8 times)
- Lasting symptoms (recorded 4 times)
- Needle marks (recorded 2 times)
- Sounds associated with treatment (recorded 2 times)

The presence, or lack, of sharp sensation seemed to be a confirming or denying factor in the belief of whether pKHA had been administered, for both the non-penetrating and penetrating KHA groups. In addition, and wide spread throughout both groups, was the comment on presence or lack of non-needling sensations. There was a belief apparent that pKHA should elicit such sensations, and therefore the absence of them suggested pKHA had not been administered. Similarly, the absence of side effects at the opinion one week post intervention seemed to influence participant's beliefs that they had not received pKHA. The needle (or cocktail stick) marks left were also a contributing factor, but only seemingly in the npKHA group. Several comments were made around the sounds that were heard: "sounds associated with needles", presumably around the sound of packaging, was a comment that swayed some participants to believe they had received pKHA. For those who were uncertain, it was often either an absence of expected sensation (either during or in the week after the intervention), or where they had observed one phenomenon but not another (for example felt small pricks in hands, but did not feel the needles were there during the 30 minute session).

## **5.10 Discussion**

The first aim of this study was to develop an npKHA approach that is believable. Between group statistical differences were not significant at both the initial opinion ( $p=0.77$ )

and opinion at one week ( $p=0.643$ ), meaning the null hypothesis, that the interventions were as believable as one another, is upheld. The second aim of this study was to assess whether it was an acceptable intervention. No adverse events were reported by the 20 participants, suggesting pKHA and npKHA approaches are safe to administer. This is in line with numerous studies investigating the safety aspects of acupuncture (MacPherson *et al.* 2001; White *et al.* 2001; Witt *et al.* 2009). In addition, there were no dropouts and all outcome measures were completed in full. These findings suggest that the intervention was acceptable to participants, and combined with achieving believability of the npKHA approach, allowed for its inclusion into the study design outlined in Chapter 7. This in line with the MRC framework for complex interventions (Craig *et al.* 2008), as it recommends that an intervention should be developed thoroughly before being evaluated. In context of the wider literature base, this study adds to the work by Takakura and Yajima (2007) and Sherman *et al.* (2002) on non-needling approaches. In addition, it has produced an original contribution to knowledge, as it is the first study to investigate non-penetrating acupuncture believability for KHA.

#### **5.10.1 Implications for future research**

Currently, the RCT with an intervention in comparison to “placebo” is considered to be the method best suited to investigating intervention effects. Thus, to ensure the highest possible quality of any research output, and therefore strengthening the reliability of any research findings, a valid non-penetrating approach to acupuncture should be implemented. In addition, the current evidence base in acupuncture intervention studies for PPGP, such as Elden *et al.* (2008), have used non-penetrating groups, and so if any future study wishes to be compared to these, their methods and methodology should also be comparable.

It is important to measure whether npKHA believability has a time frame further than immediately, and one week, after it has been delivered. Kaptchuk *et al.* (2006) found in their study that the placebo effect strengthened as time passed. For the study conducted in this chapter, it may be that some unknown variable (i.e. a placebo) on leaving the intervention room unblinds, weakens or strengthens the belief that the individual has received pKHA/npKHA. If at one week post intervention there had been evidence of unblinding, the intervention would have been considered inappropriate for use in the intervention study comparing pKHA to npKHA outlined in Chapter 7. Because within this study, both groups on average, had the same belief that they had received pKHA, treatment expectation would be controlled for in any future study comparing npKHA to pKHA. Therefore, the methods utilised in this study were adopted in Chapter 7, albeit over 6 sessions, with continued measurement of believability conducted. It was of interest to observe if this trend held over a longer time frame and after multiple acupuncture sessions, and whether any potential impact on symptoms within a PPGP population influenced needle penetration belief.

The qualitative data collected provides some insight into what influences treatment believability. As part of informed consent, the participant is given a list of potential effects they may have, subsequent to receiving acupuncture (see Appendix 4), which may have been interpreted as sensations that will be experienced if receiving pKHA, thus making the pKHA group less likely to think they have received pKHA. Chapter 3 discussed the wider evidence base surrounding placebo acupuncture, and these findings support Smith and Crowthers (2002) observations for why participants thought they had been allocated true or placebo acupuncture, as well as being in agreement with Bishop and Lewith (2008), who suggest that patients perceive needle sensation as an important feature of acupuncture. Furthermore, the findings from this study suggest that the insertion

of needles into the skin is not the only influencing factor on whether someone believes that they have received a KHA intervention. Another potential variable, that was foreseen, was the presence of red marks after receiving pKHA, hence the application of plasters to cover the needled areas. However, what was an unpredicted outcome was the presence of 'needle marks' in the npKHA group. This led some to believe that they had received pKHA, when in fact they had received npKHA, and therefore acted as a visual variable which influenced their recording on the outcome measure.

The qualitative data collected here was crucial in order to understand what influenced participants' opinion, and thus advocates further qualitative data collection within the study in Chapter 7. By asking individuals why they thought they had/had not had pKHA provides future researchers with variables that should be controlled for in order to prevent unblinding and potential subsequent reduction of credibility in the non-penetrating intervention group. In the qualitative comments, a few pointers were taken forward into the study reported upon in Chapter 7. The description to each participant for the Chapter 7 study emphasised that they; may or may not feel a sharp sensation; they may or may not have changes in their symptoms; may or may not attain deqi (non needle) sensation; and may or may not notice needle marks once removing the plaster.

In the case of the plaster to be left in situ for 24 hours, it was decided to keep this within the protocol as needle marks had some impact on belief of whether they had received pKHA, and was considered worthwhile investigating if this became more or less apparent when needling several times over a longer period. An addition to the Chapter 7 npKHA approach, following comments made by participants in this study, was the introduction of empty acupuncture packaging noises. Therefore in the Chapter 7 study, the

handling of the packaging was done in a similar way to the pKHA group, to try and control for the noise that may impact upon believability. Finally, feedback from the participants on acceptability of the procedure was that the blindfold goggles used were uncomfortable. This could have led to drop outs in the Chapter 7 study, and therefore the traditional material blindfold was administered instead.

### **5.10.2 Strengths of the study**

All interventions were carried out by the CI, meaning that the intervention delivery is likely to have been very similar for all individuals, reducing intervention delivery as a potential variable in outcomes. All participants experienced the same amount of supervision and attention, nullifying the Hawthorne effect across the groups and the therapist - participant interaction factor identified by Kaptchuk *et al.* (2008), discussed in Chapter 3. Another strength is that no dropouts occurred, and that the full quota of twenty participants was recruited, with all outcome measures completed in full. These factors suggest that the study was considered acceptable by the participants, and continued to be of interest to those who were recruited from the data collection phase to one week post intervention. Finally, from a PhD perspective, a major strength to this work is its originality. This is the first investigation into whether an npKHA approach can be believed to be a pKHA approach. This is particularly important as although Sherman *et al.* (2002) demonstrated that a toothpick can simulate needle insertion, they performed this on the lower back, whereas the study conducted here performed the investigation to the much more sensitive, and therefore more stimulus discriminative, area of the hand.

### **5.10.3 Limitations of the study**

There are several limitations to this study which are important to consider when viewing



these results. First, although having one researcher to provide the intervention to all participants helps to prevent against variability in administration of KHA, the data collection and analysis was also conducted by the intervention provider. This can raise suspicions around bias influencing results, however as part of the PhD process, the researcher here considered the involvement at all stages of the research to benefit the learning process whilst ensuring the experiment was conducted appropriately. More will be discussed on researcher bias in Chapter 7.

Another limitation maybe that some participants were not acupuncture naive, despite stating otherwise on enrolment to the study. As acupuncture is a widely used treatment within physiotherapy, and all participants in this study were physiotherapy students, it is possible that some of the participants had seen it used. There was no indication given directly that this had been the case, however the mention of acupuncture sounds does raise the question of previous exposure. The noise of acupuncture needle packaging had not been considered on study design and implementation. This potentially unblinded participants to their group allocation in two occasions in the pKHA group. However, these factors would have only strengthened the opinion that they had received pKHA, and so its impact on the outcome in this study is minimal.

Table 4 shows the demographic analysis at baseline, and demonstrates that there was a difference in age between the groups. This could have influenced results given; in this case, younger participants could be more likely to believe npKHA was pKHA, or that older participants could be less likely to believe pKHA was pKHA. Therefore, age could be an influencing factor on belief, and was therefore measured as a baseline demographic in the Chapter 7 study. Another factor to consider is that the groups were all free of ill health and not knowingly pregnant, and 20 participants are unlikely to be reflective

of the general female population. This means that the generalisability of these results are limited to the “healthy” female population, and therefore should be considered with other populations with caution. Any extrapolation to the wider population, for example the pregnant population, therefore needs to be investigated; hence continued believability assessment was conducted in Chapter 7.

Finally, the outcome measure used to assess the believability of the KHA approaches in this study has not been validated specifically for KHA acupuncture. This raises questions over the sensitivity and rigour of the outcome used, and therefore reduces the confidence in the results produced, as it may be that the outcome measure is not sensitive enough to give an accurate picture. Carifio and Perla (2007) have put forward that the use of a single Likert item is prone to fluctuating responses, reducing its rigour. However, a Likert type item has been used in previous acupuncture research, namely Sherman *et al.* (2002), so its use is comparable to published work and would seem to be the best available approach to use in the absence of a validated scale for believability. In addition, the qualitative section on why participants believed that they did or did not have pKHA helps to support the results from the Likert type item.

### **5.11 Chapter summary**

The intricate nature of placebo is an area of growing research interest, but is still largely a poorly understood concept. It is clear from the discussion in Chapter 3 that there are physical, emotional, social and environmental influences in the placebo effect, yet exactly what they are and why they exert an influence upon an individual is yet to be verified. It therefore falls to researchers in placebo trials to use an amalgamation of published work to try and control for all known factors when introducing an intervention for investigation. Questions have been raised as to what causes the placebo effect, with the

term placebo often perceived as inferior treatment approach. Yet when considering what causes the placebo effect, it is clear that it is not a single entity that has a fixed impact, more so a variable or variables that have not been controlled for between a standard care and intervention arms of a study.

It is put forward by the researcher here that researchers should report on what variables they think may have led to the changes to symptoms when compared to a control group, rather than labeling it all “placebo effect.” Researchers should report upon the importance of the ritual as much as they do on the intervention itself for the consumer of the research to understand exactly what happened in the study. Therefore in this study, the researcher has provided particular emphasis upon the intervention delivered, and has taken care to label the two interventions pKHA and npKHA (thus, not labeling the non-penetrating intervention as placebo). However, it is not the recommendation of the researcher to remove the “placebo” arm of a trial, but to emphasise all the potential variables that could have influenced the results. The results of this study indicate sensations such as pricking of the skin, observed needle marks, acupuncture noises and non-needling sensations all impact on the believability of an acupuncture approach, and not the actual insertion of a needle into the skin.

The investigation and comparison of a penetrating and non-penetrating approach to KHA allows for further insight into what impact acupuncture ritual has upon symptoms, but also provides information of how important a specific variable is on the treatment of symptoms. To do this within acupuncture, a credible non-penetrating approach should be adopted: therefore, the KHA approaches investigated here will be adopted within the study outlined in Chapter 7, continuing to measure its believability, alongside its credibility as a treatment for PPGP and its impact upon symptoms of PPGP. However, before

embarking upon the final phase of this thesis, the researcher here considered it necessary to explore the views of PPGP sufferers within the UK to inform his own knowledge of the condition, and in line with MRC framework, provide stakeholder involvement in the development of an intervention.

## Chapter 6

### Qualitative Interviews with Pregnancy related Pelvic Girdle Pain Sufferers

#### 6.1 Background literature

As part of a mixed methods research approach, this phase is considered essential not only to help inform the quantitative phase in Chapter 7, but to build upon existing knowledge of PPGP, and produce the first UK based study on the experience of PPGP by pregnant women. This is especially important given that the discussion in Chapter 2 highlights PPGP may not be a uniform experience, with wide varying incidence rates reported in different countries (see Table 2, page 31). A review by Kanakaris Roberts and Giannoudis (2011) put forward that of the trials that most closely fit the Vleeming *et al.* (2008) definition of PPGP, the incidence of PPGP is between 16-25% of pregnant women. However, a longitudinal study based in Norway by Dørheim, Bjorvatn and Eberhard-Gran (2013) found that PPGP was the reason for sick leave in 31.8% of cases. Similarly, Ramachandra *et al.* (2015) performed a survey with 261 pregnant women in India who attended antenatal physiotherapy classes, and found that 37% of the women experienced PPGP. Bjorkland and Bergstrom (2000) found PPGP incidence rates of 49% in Sweden, 77% in Finland, 66% in Tanzania and 81% in Zanzibar, and concluded that there may be a sociocultural aspect to symptom manifestation. This diverse presentation of PPGP, which could depend upon geographical location, provides a rationale for this study as a standalone exploration of experiences whilst producing an original contribution to knowledge, despite a number of studies being published prior to the data collection and analysis phase of this chapter.

As discussed in Chapter 4, stakeholders are an important consideration when looking to evaluate an intervention (Craig *et al.* 2008) and thus should be consulted within the development phase prior to implementation. Qualitative research is the most appropriate method when looking to conduct an in-depth exploration of peoples' experience on a given condition (Cresswell, 2014), such as PPGP. Chapter 2 served to highlight how healthcare professionals views may influence patient care (Mogren, Winkvist and Dahlgren, 2010), and therefore subsequently their experience of PPGP. Qualitative studies such as the 28 one to one interviews in Wellock and Crichton (2007), and the 27 one to one interviews in Elden, Lundgren and Robertson (2014a), both analysed through thematic analysis, demonstrate that the PPGP sufferer considers the health professional important in managing PPGP.

In addition, support mechanisms would appear to extend beyond the healthcare professional, with Elden, Lundgren and Robertson (2013), Persson *et al.* (2013) and Engeset, Stuge and Fegran (2014) all reporting that close family and partners had an important role to play in management of their PPGP. However, with Wellock and Crichton (2007) failing to report their methods in any real depth, Engeset, Stuge and Fegran (2014) being very descriptive in their findings and Elden, Lundgren and Robertson (2014a) failing to acknowledge their philosophical and reflexive standpoint, further work was advocated to explore who, if anyone, was considered an important part of a support network by UK PPGP sufferers. The above literature influenced and provides rationale for the interview guide (see Appendix 10) in the study outlined in this chapter, as it would appear that part of the PPGP experience includes healthcare professionals, close family and partners.

Another recurring thread through the existing qualitative literature is that there is a lack of understanding surrounding PPGP by sufferers. The women in the study by Wellock and

Crichton (2007) stated that they were 'shocked by the pain they experienced, it was so unexpected', suggesting information provision was not always timely, and is supported by subsequent research by Elden, Lundgren and Robertson (2014a) who recommend information on likely sensations, to be given to pregnant women early on in pregnancy. The lack of information provided to patients was also highlighted by Persson *et al.* (2013) and Engeset, Stuge and Fegran (2014), with Fredriksen, Moland and Sunby (2008) postulating that if introduced earlier in pregnancy, it could aid with coping and anxiety levels. This has yet to be explored in a UK population, therefore when conducting the interviews for the study in this chapter, it was important to explore whether the PPGP experience also involved lack of information. In fact, as there is currently no qualitative work published exploring UK women's views on PPGP, there are a number of features of PPGP that need further investigation, such as the symptoms experienced.

Current European guidelines (Vleeming *et al.* 2008) for PGP management consider only physical symptoms and do not discuss the psychosocial impact, and are not specific to PPGP sufferers. To focus upon the physical aspect of PPGP, Stuge *et al.* (2011) developed the Pelvic Girdle Questionnaire (PGQ) to measure pain and function, which was demonstrated to have validity and reliability in a subsequent study by Grotle *et al.* (2012). Not surprisingly, qualitative studies have also highlighted impact on pain and function, with Elden, Lundgren and Robertson (2013), Elden, Lundgren and Robertson (2014a), and Engeset, Stuge and Fegran (2014), all reporting that during interviews women portrayed these as problematic symptoms. Therefore the interview schedule in Appendix 10 provided focus on symptoms to allow for an exploration of the PPGP physical experience. In addition, although the literature discussed in Chapter 3 vindicates the use of an outcome measure that attempts to measure ADL, it is unclear as to whether pregnant women in the UK would consider the PGQ to be an appropriate reflection of

their symptoms. Therefore, included into the interview schedule for the study outlined in this chapter, women were asked their views on the PGQ's suitability.

Furthermore, a number of qualitative studies have put forward the psychosocial impact of PPGP. Mogren, Winkvist and Dahlgren (2010) found that midwives felt PPGP impacted upon their patients mood, Bjelland *et al.* (2012) suggested reducing emotional distress could lower the impact of ppPPGP and Persson *et al.* (2013) went into a lengthy discussion on how PPGP could effect the psychological wellness of the pregnant women. As put forward in Chapter 2, in order to gain a deeper insight of the woman's experience of PPGP, an exploration of these symptoms in a UK based population was conducted within the study outlined in this chapter.

This phase of the thesis aims to explore PPGP as experienced by UK women, noting whether prominent findings from current literature such as information provision, support of others, and symptoms of PPGP are of similar stature. This chapter contributes the largest qualitative part to this mixed methods thesis, and as Craig *et al.* (2008) state in the MRC framework, provides an important part to an interventions development, through the use of stakeholders' views in study design and implementation. This chapter not only informs the KHA investigation outlined in Chapter 7, thus providing a level of stakeholder input into the study method, but is also a standalone piece of research. To the author's knowledge, this study is an original contribution to knowledge through; being the first UK based exploration of PPGP sufferers views; providing discussion around interviewee's expectations of treatment; being the first to adopt a pragmatic philosophy in exploration of PPGP views; expressing views of PPGP sufferers upon the Pelvic Girdle Questionnaire (PGQ) and; being the first exploration of views upon PPGP by a male lead author.



## **6.2 Study Aim**

The overall aim of this phase was to gain an understanding of PPGP as experienced by women in the UK.

## **6.3 Methods**

A qualitative approach was adopted, using one to one semi-structured interviews similar to the non-UK based studies discussed earlier. It was conducted in a women's health physiotherapy department with eight women. The number of participants was considered to reflect the recruitment of Persson *et al.* (2013), who indicated that a level of data redundancy was achieved by the eighth interview, Engeset, Stuge and Fegran (2014) who interviewed five women and Mogren, Winkvist and Dahlgren (2010) who interviewed ten women. Studies such as Elden, Lundgren and Robertson (2014a) interviewed 21 women, yet this was a large scale study conducted by numerous authors which would have been unmanageable as part of a programme of research conducted as part of a PhD. Semi-structured interviews have been chosen over an unstructured interview, as it is believed to be a more appropriate method of gaining more specific information (Bowling and Ebrahim, 2005), and was the method of choice in the aforementioned qualitative studies.

## **6.4 Ethics**

Approval has been sought and granted by the Faculty of Health and Life Sciences Research Ethics Review Panel 24th October, 2013, ref. number: RE-HLS-12-130701-51d1815248c3f. It was then passed for ethical approval via Newcastle and North Tyne-side 1 NRES Committee 2.4.2014, reference number 14/NE/0060, 7th April 2014 (see Appendix 24 and 25).

## **6.5 Sampling and recruitment**

Convenience sampling was adopted as those recruited were from the area where the feasibility study would recruit from, and was local to the researcher. The women were recruited from a women's health physiotherapy department located in the North East of England. They attended their usual physiotherapy department appointment, and if they were diagnosed by the physiotherapist as having PPGP, were asked by the physiotherapist if they would be interested in discussing the study with the researcher. If a woman decided that she wanted to be involved, she was given a participant information sheet (see Appendix 9), outlining the study aims and what it required of them. The researcher was then contacted by the potential interviewee to arrange a mutually convenient time to conduct the interview.

## **6.6 Data collection**

Several considerations were taken into account prior to beginning the interviews. First, an interview schedule was produced to help guide the interviewer. In accordance with the suggestion of Rubin and Rubin (1995), there were main and probing questions (see Appendix 10). The main questions were global and open ended, designed to allow individuals to discuss their own views of their experience of PPGP (Liamputtong, 2009). All questions had neutral wording, as suggested by Turner (2010), which was integrated to help avoid asking leading questions (Liamputtong, 2009). The probing questions were there to help gain further insight, or to help obtain an optimal response (Turner, 2010). According to Rubin and Rubin (2012), these interviews would be considered a topical interview style, as the interviewer is looking for specific facts and descriptions of what it is like to have PPGP. Although strictly speaking, there can be no right or wrong questions, the researcher felt that by consulting the existing literature it would help to ask questions surrounding issues that have previously been identified by Persson *et al.* (2013),

Mogren, Winkvist and Dahlgren (2010), Wellock and Crichton (2007) and Elden, Lundgren and Robertson (2013). Therefore, the questions asked were as a result of the researchers understanding of PPGP, and would therefore have had some influence on the data obtained. The interview schedule (see Appendix 10) was visible to the researcher throughout each interview as an aide memoir. Field notes were taken, however written after the interview to attempt to make the interview more qualitative and less clinical.

The participants were told that interviews would last for approximately 1 hour and be audiorecorded, and would be conducted within the women's health physiotherapy department. The participants were invited to bring a chaperone if they wished. It was decided by the researcher to conduct the interviews in the physiotherapy department from where the women would be recruited, as it would be familiar surroundings and would hopefully reassure the women that as they were in hospital, the interview would be performed in the strictest of confidence. It was also considered that being a male discussing a problem that is female orientated, it may help if the interview was somewhere they were already comfortable with. The interviewer did attempt to put the women at ease by dressing professionally, adopting a relaxed atmosphere and trying to be as conversationalist as possible. In addition, the advice given by McNamara (2009) on their considerations prior to beginning an interview (see Table 9) were embraced.

**Table 9 - Considerations prior to interviewing (McNamara, 2009)**

<b>McNamara's considerations</b>	<b>How the consideration was acted upon</b>
<b>Select a setting with little distraction</b>	<i>rooms were free of distraction of a telephone and a sign put on the door asking for no interruptions</i>
<b>Explain the purpose of the interview</b>	<i>explained in the informed consent procedure and immediately prior to interview beginning</i>
<b>Address terms of confidentiality</b>	<i>explained in the informed consent procedure and immediately prior to interview beginning</i>
<b>Explain the format of the interview</b>	<i>explained in the informed consent procedure and immediately prior to interview beginning</i>
<b>Indicate how long the interview will likely take</b>	<i>explained in the informed consent procedure and immediately prior to interview beginning</i>
<b>Methods of how to get in touch if need to in the future</b>	<i>provided women with contact telephone and email address</i>
<b>Ask if they have any questions before you get started</b>	<i>included within the discussion prior to beginning the interview</i>
<b>Don't count on memory to recall answers</b>	<i>addressed by using an audiotape recorder/ Dictaphone</i>

## 6.7 Data analysis

Numerous authors have criticised the lack of detail in data analysis sections of qualitative work (Liamputtong, 2009); without this, the context of the data reduction/display is difficult to understand and can lead to a lack of transparency on how researchers came to their conclusions. This is known as dependability, and when present allows the reader to examine the adequacy and logic of the conclusions made (Liamputtong, 2009). It is therefore suggested that researchers explicitly outline their data analysis process, and to make clear their reflexivity (or from a pragmatism viewpoint, the researchers warranted beliefs).

For this study, a thematic analytic approach was adopted in the analysis of the data. Thematic analysis, although having its origins in grounded theory, is put forward by Carpenter and Suto (2008) as a foundational approach to any qualitative data analysis (Carpenter and Suto, 2008). When considering how to analyse large amounts of qualitative data, Robson (2011) stated whatever approach is taken, the researcher has the responsibility of describing it in detail. Thematic analysis was the approach adopted by Waterfield *et al.* (2015), Persson *et al.* (2013), Engeset, Stuge and Fegran (2014) and Elden, Lundgren and Robertson (2014a), and so therefore has precedence and thus advocates the approach for a PPGP population. The approach taken here followed five broad steps. The terminology used is not as important as what each stage represents; there appears to be a confusing interchangeability of words used to describe each of these phases depending upon which textbook is read. Therefore, the researcher here felt it important to state clearly what is meant by words such as 'code' to ensure the reader is able to follow the data analysis/synthesis process, and has outlined the terminology used below:

- Data collection (the interview, field notes immediately after each interview, and transcription of the audio tapes)
- Pre-coding (cutting and pasting raw data from the transcriptions to a pre-coding file. Adopted for each interview individually)
- Coding (labeling raw data under a subheading that encompasses a commonality between the raw data extracted)
- Categorisation (analysing the codes that have emerged from all interviews and grouping codes together that have similarity. Then a category label is produced which the researcher feels accurately reflects what the codes are saying)
- Themes (the synthesis of categories into broader conceptual pods. The themes are what are used to present the findings of the research, and are presented to describe the data produced)
- Discussion (interpretation of the findings presented in the themes, integrating previous literature to support the interpretations made whilst highlight areas of original knowledge)

The data analysis began during the interviews in the form of field notes that the researcher made immediately following each individual interview. This process is important as it allows for an immediate reflection of the interview on issues such as how the researcher felt, and the general impression that was made at that time (Carpenter and Suto, 2008). These field notes were then consulted throughout transcribing, coding, categorisation and creation of themes to allow for context to be provided. One month following the interviews, the researcher familiarised himself with the audiotapes by playing back the interviews via a dictaphone. Next, each interview was transcribed verbatim, a time consuming process but one that helped immerse the researcher in the raw data and

gain an understanding of the meaning of what was being said and the spirit of the conversation. To allow for ease of audit trail, each transcript was assigned a unique colour. This meant that when looking at large amounts of raw data during the coding and categorisation process, the researcher could trace the origin of the text if further clarity was needed (see Appendix 11 for raw data).

The next stage was to begin pre-coding and coding the raw data. Because the process of coding involves using raw data and for it to be compared to and applied to other similar raw data, it is often referred to as constant comparison analysis (Robson, 2011).

To begin with, a pre-coding approach was taken; this involved cutting and pasting chunks of text into a new word document, which appeared to be relevant to the research question, or that seemed to be of particular importance to the pregnant woman. This process was done for each interview individually. Then, the coding process involved assigning these chunks of raw data to a word or phrase (a label) which the researcher considered to best represent what the interviewee was saying. There was a process of rewording these labels as the coding process developed to find words that better suited the description of the raw data. As the coding process developed, new codes were added, and when new codes were added, the previous interviews that had been coded were revisited to see if similar raw data was present but had been overlooked first time around.

This process allowed the researcher to begin to form ideas of the main issues that were being portrayed by the pregnant women, which naturally led onto the categorisation process.

The researcher found that the categorisation process was not as time consuming to complete as the transcription/coding stage, yet required a large amount of revisiting the original transcripts for accuracy to try and ensure there was no mis-interpretation of the

data. The field notes were useful here as it helped to keep the context of each interview. The categories created, ten in total (see Table 10), were a phrase which the researcher considered best represented a group of codes. This process was important in the data reduction stage making the data more manageable when creating the themes. To report on the findings of this study accurately and concisely, themes were produced to help give the reader an overall sense of what the researcher considered to be the most important issues surrounding PPGP. The four themes were made up from the ten categories, and again, the raw data was consulted to ensure that each theme gave a fair and accurate representation of what the women had said. The researcher believed that by presenting the themes descriptively first, it would help the reader to understand what made up that theme. The discussion section that followed provides; more interpretation of what these themes could mean; how the themes add to the knowledge of PPGP; and why these findings may be used to inform future research. Because this thesis is mixed methods research, the findings were given some consideration in relation to how they may influence the study in Chapter 7, where women would be involved in research investigating KHA for PPGP.

Within and between each stage there was a process of constant comparison, whereby the raw data was continuously checked and rechecked to try and ensure that the analytical process was within context of the original interviews. The researcher also had a conscious awareness of his warranted beliefs at all times when analysing and synthesising the raw data into more manageable chunks. The considerations that need to be taken into account when the researcher is making conclusions about the data, is that humans as natural analysts have deficiencies and biases corresponding to the problems that they have as observers (Robson, 2011). It can therefore be suggested that as long as the researcher presents an awareness of how their own biases may have impacted upon



the data analysis and presentation, the reader can interpret the findings in such a light. Although from a pure pragmatism stand point, no two experiences can ever be the same for different people, and therefore it cannot be expected that an external reader would interpret the raw data exactly as how the researcher here has, the shared beliefs consideration allows for the reality that any data that has been produced can be read and understood by others whom have knowledge/experience of PPGP. Therefore, it is important to contextualise the data collection and analysis process clearly enough to a reader whom has not been involved in this research.

## **6.8 Reflexivity**

Reflexivity is important to acknowledge if adopting pragmatism as a paradigm, and is considered to be imperative to discuss when presenting qualitative research in order to contextualise the data analysis and synthesis reported upon (Carpenter and Suto, 2008). Warranted beliefs can change over time, and so if they had between analysing interview one to interview four to interview eight, it may alter the way the data is perceived and therefore presented by the researcher. The researcher felt that despite being a novice qualitative researcher, his experience in interviewing for undergraduate university places aided his ability to gain information from each participant. However, perhaps more of an influence was the researchers 10 years' experience as a clinician where he regularly interviewed individuals with complex health needs. In order to help their patients, clinicians need to develop a rapport with each person whilst still keeping the interviewee on the issue at hand. Although the researcher wanted to explore PPGP without dictating too much, it meant he felt comfortable directing the interviewee if it was considered that the conversation had diverged too far from PPGP. Throughout the data gathering and analysing process, the researcher made notes on his reflexive position. The researcher felt he had a sympathetic view towards pregnant women, primarily because he was aware of

the lack of treatment options available to them. Although a heuristic approach to research is an accepted paradigm (as outlined in Chapter 4, page 91), the ability to observe the data from a purely observers standpoint can also provide a unique insight into the condition (Patton, 2002). Being male, and therefore never having experienced PPGP, provided an observer's viewpoint whilst providing a unique and original piece of research investigating views on PPGP, as there is currently no literature that has used a man as the primary data synthesiser. This could have prevented some women from discussing issues of a more personal nature, thus not providing a deep insight into the problems they face. However, on reviewing the existing qualitative literature that had been conducted by women, it does not seem that more personal conversations were had. In addition, some women in this study were very open about the emotional side to their PPGP, seemingly the researcher being male not hindering the data gathering process.

The researcher had attempted to distance himself from existing qualitative work, in particular the themes and conclusion drawing stages, to try and prevent other researchers' findings influencing the data reduction and display in this study. However, it cannot be guaranteed that subconsciously, a general awareness of the literature on PPGP could have encouraged more focus upon certain areas of the transcripts than if he had been a complete novice to the area. As noted earlier, the questions asked were partially based upon the existing literature, so in turn could have influenced what data was collected. It is also important to highlight the position of the researcher during the data analysis process. The researcher was within a busier time of his working calendar, and therefore may have been tempted to take a more superficial approach to the data extraction and synthesis. This was attempted to be removed as an influencing factor by revisiting the work at a less busy time period, and encouragingly, this does not seem to have been an

issue.

The researcher also became aware of a subtle change to his warranted beliefs surrounding PPGP and pregnancy in general. Although, being a healthcare practitioner for over 10 years, he was already aware of the impact upon psycho-social aspects of health following an ailment, it became more apparent as each interview was coded and categorised how much of an impact this had. Therefore, being aware of this subtle change, constant comparison was adopted on a larger scale by revisiting the interviews to observe whether any other details surrounding psycho-social issues were present and had been missed initially. Although there were no significant alterations to the data extracted, reading the interviews with an altered warranted belief could have changed the emphasis on interpretation of certain topics discussed.

## **6.9 Results**

This study recruited eight women within a four week period. The shortest interview lasted 50 minutes with the longest 1hr 10 minutes. One woman opted to have her grandmother present during the interview, with all other women preferring to attend by themselves. The age of the women interviewed was between 20-29, gestation between 21-30 weeks with time suffering from PPGP ranging from 5 to 14 weeks. Highest education level ranged from NVQ to degree, with most women not exercising at all, though one woman did record 20-30 hours per week. Therefore, because of the ease of recruitment and range of demographics of those who were interviewed, it is considered that this method of research could be expanded into a larger format. Table's 10-13 provides an overview of which codes and categories informed the four themes which the researcher here considered to best represent the interviews undertaken. The four themes are displayed as: 'The reality of PPGP'; 'Support mechanisms most important in PPGP'; 'Vulnerability';

and 'Knowledge is power'. The categories that made up each theme are given as sub-headings (in italics), with raw data provided to support each theme/category, followed by the participant who provided it in brackets.

**Table 10: Codes and Categories generated from interviews: The reality of PPGP**

<b>Codes that informed Categories</b>	<b>Categories that informed themes</b>	<b>Theme</b>
Duration Onset Process of diagnosis Description of symptoms	Onset of PPGP	The reality of PPGP
Being pregnant Not fun Health Sacrifice Impact on ADL's Psycho-physical impacts other than pain Social impacts Feelings of guilt	Impact on psycho-social	
Expectations Suitability of the PGQ outcome measure Preventative measures	Expectations of PPGP	

**Table 11- Codes and Categories generated from interviews: Support mechanisms most important in PPGP**

Codes that informed Categories	Categories that informed themes	Theme
<p>Advice from medical professionals</p> <p>Expectations of physiotherapy</p> <p>Negative support from others upon managing PGP</p> <p>Successful treatment</p> <p>What has reassured you about your pains</p> <p>Trust</p> <p>Preventative measures</p>	Healthcare experience	Support mechanisms most important in PPGP
<p>Support from others</p> <p>Helplessness from significant other when trying to describe PPGP</p> <p>Sympathy from others</p> <p>People being understanding</p> <p>Negative support from others upon managing PPGP</p> <p>Reassuring</p>	Support from family and friends	
<p>Successful treatment</p> <p>What do you want to know about a treatment</p> <p>Use of painkillers</p> <p>Impacts treatments have other than pain</p> <p>Desirables</p>	Treatment	

**Table 12- Codes and Categories generated from interviews: Vulnerability**

<b>Codes that informed Categories</b>	<b>Categories that informed themes</b>	<b>Theme</b>
How other women must feel	Perceptions of others	Vulnerability
Worry Self-Doubt I think I'd do it again for my baby Fear Lack of control Coping until birth	Fear	

**Table 13- Codes and Categories generated from interviews: Knowledge is power**

<b>Codes that informed Categories</b>	<b>Categories that informed themes</b>	<b>Theme</b>
Not knowing Prior knowledge of PPGP Original thoughts on what the PPGP was	Importance of Knowing	Knowledge is power
Looking up the problem Knowing the seriousness of the problem Prior knowledge of PPGP Original thoughts on what the PPGP was Fear Worry and self-doubt Not knowing How would you have reacted if someone had had this kind of pain? Knowing others have had the same problem What do you want to know about a treatment	Looking up the problem	

### 6.9.1 The Reality of PPGP (Table 10)

*'if I was to let myself know what I was in for I think maybe I would probably be a lot more terrified at getting pregnant' (P 4)*

As a natural introduction to the interviews, the interviewee's were asked about their symptoms and how they affected them. This led to a significant amount of data focusing upon the course of PPGP, and thus resulting in this theme. Prior to this study, the symptoms of PPGP have been investigated using qualitative methods almost exclusively in Scandinavia, so the researcher considered it not only reflective of what the participants discussed, and in most detail, but also important to report upon to allow for comparison to the existing literature. What was apparent throughout the interviews was that the pain impacted heavily on all aspects of their life, not only from a discomfort perspective, but also due to restrictions imposed by such a discomfort, such as ADL's and the general wellbeing of the individual. Descriptions of how PPGP felt physically were consistent with the European guidelines (Vleeming *et al.* 2008) definition statement, and concurred with findings from most of the literature outlined earlier in this chapter (Elden, Lundgren and Robertson, 2013; Elden, Lundgren and Robertson 2014a; Engeset, Stuge and Fegran, 2014; Mogren, Winkvist and Dahlgren, 2010; Persson *et al.* 2013 and; Bjelland *et al.* 2012).

#### Onset of PPGP

Women described the onset of PPGP as insidious, and always within the second trimester. They either sought out medical advice early on because they were concerned about the pain being sinister in nature, or left seeing a medical professional until the pain became more intense/more frequent. Those that had had back pain in the past stated that they delayed going to see a health professional, with the participants discussing seeing either their doctor or midwife, with no real reasons put forward as to why they

sought one or the other. There was a stark contrast in what most of the women had thought pregnancy would be like to what their actual experience was:

*'I kind of imagined this kind of fairy tale maternal bloom type thing it would just happen and I would feel great and it would all be wonderful I think I was maybe a little naïve about it' (P2).*

More specifically related to PPGP, they described symptoms as *'just an unbearable pain'* (P1) or that *'constantly feeling your pelvis is going to fall off its horrible...'* (P8) with one woman exclaiming that at times she has felt:

*'...my baby is just going to come out.'* (P4).

#### Impact on their psychosocial state

Most of the participants spoke about how their mood had changed considerably since developing PPGP, and although some acknowledged that this could be due to general pregnancy, there was a definite emphasis that the pain was to blame:

*'it hurts so it does make you emotional it doesn't help with the hormones that you have when you're pregnant as well so you think everything's ten times worse' (P3).*

The change in mood was always portrayed as negative and usually put into context of how it impacts on what they want to do:

*'it's making me sad [laugh] cos I can't... get on and do things as normal I just want to get on with life' (P2).*

It also became clear that the PPGP not only impacted upon their mood, but also their ability to function in their usual social surroundings:

*'am normally like a social active person and it has made me the most miserable anti-social person I don't want to speak to anyone I don't want to go anywhere cos I'm in too much pain' (P3).*

It was common ground for the participants to speak of staying at home more frequently:



*'don't really go out much I just speak to my friends over the internet' (P5).*

The PPGP was now the focus in these women's lives, and so dictated their daily life when it came to socialising with friends:

*'I'm just avoiding making plans altogether... I can still go out and do them but after half an hour I'll be limping and things are obviously really really uncomfortable and really are groggy and grouchy and are I'm not good company once it sets off [laugh] I'm not pleasant conversation once I'm in pain' (P4).*

The interviewees were shown the PGQ, which asks questions around functional activities that may be effected by PPGP, and asked if they felt it relevant to the types of problems they had as a result of suffering with PPGP. The response was of agreement with the PGQ:

*'I find all of that hard so yeah it's most things what people with this pain would suffer with and have to deal with most of them so yeah definitely' (P1).*

However one woman did point out that:

*'you might not get good answers to because of the fact that the other impacts pregnancy has' (P2).*

### Expectations of PPGP

Most of the women described their symptoms as:

*'over the next few weeks I think it's going to get worse' (P7),*

and directly attributed this to getting bigger as the pregnancy developed, demonstrating a relationship that the women had formed with increase in abdomen size and PPGP. Despite this connection between pregnancy and increase in PPGP, none of the women displayed or discussed any resentment towards the pregnancy or unborn child.

There was also a sense of hopelessness about PPGP:

*'it's not something that's fixable ...it's just getting the pain under control' (P6).*

However, the general feeling was that:

*'the limitations to what I can do I know that that is only temporary' (P4)*

and that:

*'I hope it will just go away obviously after all the weight has gone and everything gets back to normal after I hope it just obviously fades away' (P5).*

**6.9.2 Support mechanisms most important in PPGP (Table 11)** *'I think I would be lost I really do there really is an emotional side to it you can sort of deal with it a bit more when you talk with other people' (P2)*

Support mechanisms were frequently discussed and supported views expressed by previous researchers (Elden, Lundgren and Robertson, 2013; Persson *et al.* 2013 and Engset, Stuge and Fegran, 2014). Throughout the interviews, the women talked of how PPGP affected others' behaviours towards them, and how the interpretation of PPGP by the other person affected them. There was a palpable sense of:

*'nobody ... taking it seriously' (P8),*

and when the interviewee perceived a lack of empathy, it was usually followed by a sense of loneliness, though this word was never used. In particular, the one woman whom seemed to have been affected the most, spent a considerable amount of the interview expressing her views on how others, whether family, partner or health professionals, gave little empathy:

*'I just feel like nobody understands what I'm going through' (P8).*

This was made more apparent where those women who felt they had the support of significant others, could imagine a scenario much worse than their current state if that support was not there:

*'I think I would be lost I really do there really is an emotional side to it you can sort of deal with it a bit more when you talk with other people' (P7).*

Interviewees discussed these support mechanisms in independent terms, separated into family and friends, then health professionals, and were originally coded and categorised as separate entities. Family and friends were discussed in a more emotional support capacity, whereas health professionals were seen as gatekeepers to information and practical advice. However when the researcher considered the raw data for underlying commonality, it was considered by the researcher that empathy and practical advice provided a support mechanism.

#### Support from family and friends

Support from family and friends dominated the interviews, and was considered integral to dealing with PPGP:

*'Definitely reassuring... to know that your mum went through it....people forums...friends who've had babies... nothing they can do but just to listen to you moan about it this helps' (P7).*

The women also could imagine what it would be like to not have the support:

*'...I think I would be lost I really do there really is an emotional side to it you can sort of deal with it a bit more when you talk with other people' (P1).*

This support was clearly not just from partners but friends as well, with one woman indicating how valuable that support was, as she had planned a replacement support mechanism:

*'Well I know I would struggle cos he is away now in Amsterdam till Monday so I've got friends coming to stay with me so I'm not on my own.... I'm really lucky cos he's really good' (P5).*

In support of these predictions, one woman expressed that

*'I wasn't in the best relationship anyway so I think that made it even though it was bad that made it 20 times worse...'(P8).*

### Healthcare Experience

The participants frequently regarded healthcare professionals as a valuable source of knowledge. Women described healthcare contact with Doctors, midwives and physiotherapists, and that mainly it was a positive experience:

*'...was just good to talk to somebody who I knew was actually a professional em and let them know what was going on so if something needed to be done it could be done and then at least I knew that anything that was in my power to do I had done' (P6).*

Health providers, in particular physiotherapists, seemed to have a pivotal role in supporting the pregnant woman:

*'she gave me so much more information which was really really helpful...she talked to me about it she told that yes its related to your pregnancy...what it means...she gave me quite a bit more information about it and gave...some measures in place for a long-term solution so I when I walked out of the discussion...I felt a lot better. I felt like the information had helped at least...I felt I had more understanding about it because up to that point I was pretty much completely in the dark' (P4).*

There were several incidents where the women felt they had not had adequate support from the health professional, usually based upon on how much or the quality of information that was given. One participant was hospitalised due to the pain, and felt the response from some of the health professionals was negative:

*'...had one nurse she wasn't very good...she basically said that I'm damaging my baby. She said that do I want my child to have withdrawal symptoms' (P8).*

### treatment

The interviewee's all discussed what they would consider to be a successful treatment, ranging from reduction in symptoms to complete resolution:

*'...I know there's no miracle cure nothing's going to make it go completely...anything that even just took it away a little bit is helpful...even if it just reduced it just a little bit' (P6).*

The women considered treatment to be successful if it either reduced the pain or allowed them to perform more functional tasks, however there was a trade off on the practicality of seeking out a treatment:

*'To come in (to hospital) once or twice a week I would it would probably have to stop the pain altogether to be honest just because once or twice a week is a bit out of my way' (P5),*

and that:

*'I'd rather go through pain and know my baby's ok than put it at risk' (P3).*

There was a difference in opinion on the taking of painkillers:

*'you can't take medication when you're pregnant apart from paracetamol and that doesn't work... If it was safe for the baby fine if it didn't affect the baby' (P7),*

with another woman stating:

*'I've got co-codamol as well like a low dosage' (P2).*

However the recurring comments made was that a Doctor would not prescribe medication that was thought to be potentially harmful to the foetus.

**6.9.3 Vulnerability (Table 12)** *'I was really really worried that if something happened to my son what was I going to do if he fell over' (P4).*

Perceptions of others

Several women commented upon how they felt they were perceived by others, and it was always a negative outlook:

*'I think potentially it wouldn't even be taken seriously for someone who had never experienced anything like it before' (P6).*

If others had had pain during pregnancy, or a similar pain issue such as LBP, it was felt that those people were more empathetic towards the pregnant woman's plight:

*'there's a girl that I work with who has sciatica just general sciatica em and she's very sympathetic about it and she will offer to do things like do the heavy lifting...and she'll kind of understand the limitations of it a bit more' (P4).*

However, not all women wanted to be treated any different, and were a little frustrated at how others had changed their approach to the pregnant woman:

*'people seem to think that I'm like a fragile little china doll because I'm pregnant not because I've got pain just because of the fact that I'm pregnant' (P3).*

None of the women expanded upon this, and so it is impossible to say if empathetic actions were more apparent in people who had had similar pain experiences, leading the pregnant women to feel they understood and empathised better. Perhaps the PPGP sufferer surmised it must be because of the other person's experiences, or the belief of empathy arises from the pregnant woman believing the other can only truly empathise if they had experienced a similar problem.

## Fear

Fear and worry were noted throughout the transcripts, and although not every person emphasised this, it did appear as a running thread. The fear was in context of a serious health concern:

*'I just thought I was losing the baby' (P6),*

and

*'I didn't really know what it was cos I said I had been up all night with really bad back ache...I didn't know if it was something serious' (P3).*

However, fear and anxiety also extended beyond health concerns:

*'since I've become pregnant I just get a bit nervous I feel better if I know there is somebody here' (P7).*

There was also concern that the disability of PPGP impacts on the ability to care for others, in particular other children:

*'I was really really worried that if something happened to my son what was I going to do if he fell over' (P4).*

However, fear and anxiety was not described in relation to expectancy of continued symptoms of PPGP post-partum.

**6.9.4 Knowledge is power (Table 13)** *'I think that now that I've got more information about it its less big and scary is the main thing' (P2).*

The amount of discussion around this topic was not predicted, and the amount of knowledge, or lack of, seems to be a huge influence on PPGP. This has already been identified by researchers such as Persson *et al.* (2013), Fredriksen, Moland and Sunby (2008), Wellock and Crichton (2007) and Elden, Lundgren and Robertson (2014a). Such was its presence, it has meant that all of the other themes previously discussed have

strong links to this theme. After much deliberation, the researcher decided that its presence merited it as a theme in its own right. In general, the information surrounding PPGP pre diagnosis was scarce:

*'it's something that isn't out there it something that they don't tell you' (P6),*  
and it often came as a surprise to the women when they developed PPGP.

### Importance of knowing

The interviewee's expressed that having little knowledge of the reason of having pelvic pain impacted upon the symptoms:

*'it was quite bad at the beginning not knowing what it was' (P1).*

The participants were unsure of how it would progress and what it may mean for labour

*'I'm terrified actually to be perfectly honest' (P6).*

One of the women, who was hospitalised for a period of time because of the pain, suggested that the lack of diagnosis, and therefore knowing why she was suffering with pelvic pain, contributed to her hospital stay:

*'if I had of know it was this (PPGP) then I would have left' (P8).*

Perhaps the most striking comment of:

*'I just thought I was losing the baby' (P6),*

demonstrates the level of distress not knowing can create. However, once the participants had been given information, specifically from a healthcare professional, it had a positive impact on their outlook:

*'I'm alright with it cos I think it's like I know what it is now' (P7),*

and:

*'hearing that it was manageable was quite a relief' (P1).*



One woman's comments, already displayed in '6.8.2 Support mechanisms most important in PPGP' sum up how giving information around PPGP, and the process of giving a label to their symptoms, can have an impact:

*'she gave me so much more information which was really really helpful cos although the pain hadn't changed at all now some of my other symptoms are starting to abate so the pain in some way seems more prominent em but she talked to me about it she told that yes its related to your pregnancy em it's called this this is what it means em she gave me quite a bit more information about it and em gave me some ways of putting things in place of how to I suppose not manage it or cope with it because the pain hasn't changed at all but at least put some measures in place for like a long-term solution em so I when I walked out of the discussion with [physiotherapists name] I felt a lot better. I felt like the information had helped at least... I felt I had more understanding about it em because up to that point I was pretty much completely in the dark' (P4).*

#### Looking up the problem

The easy access of the internet resulted in all participants reporting using it as a means of finding out either what their symptoms mean, or what the diagnosis of PPGP was. The internet was a source of information for all of the women interviewed, with different websites providing different roles. The NHS website was mentioned by seven women in terms of gaining facts, and was considered a reputable source by all:

*'everything the NHS tells you is right and its true about SPD and stuff like that... the NHS got the facts about why' (P2).*

However, women were using the internet for answers, and were choosing to use the NHS as a trusted and reliable source, but were left with little in the way of help. Despite it being considered a reputable source and helpful for a general understanding of PPGP, it

wasn't enough for most women interviewed:

*'a lot of the information that was on the NHS website was quite generalised' (P3),*

and:

*'too much for me because I don't understand all the jargon words' (P1).*

In order to find further information, women turned to social media based websites, but all acknowledged the shortcomings of blogging sites:

*'Even crazier too specific and that's where half the horror stories come from as well where kind of em I think people have clearly needed an outlet for their stories or for their experiences that have happened to them...and then you're kind of perception of what's usual and what will always happen in pregnancy is really quite skewed' (P5).*

Despite the wide spread use of the internet as a source of knowledge, there was also a recognition that websites alone were not sufficient:

*'you need to hear it from your doctor or your midwife you can't just I don't like self-diagnosing myself anyway you just worry yourself and go into a panic' (P4),*

and:

*'was just good to talk to somebody who I knew was actually a professional em and let them know what was going on so if something needed to be done it could be done and then at least I knew that anything that was in my power to do I had done' (P3).*

## **6.10 Discussion**

The ease of recruitment to this study, combined with the rich data provided by each participant, suggests that this study could be extended into other PPGP populations within the UK. To the author's knowledge, this study adds several original contributions to knowledge through; being the first UK based exploration of PPGP sufferers views;

providing discussion around interviewee's expectations of treatment; being the first to adopt a pragmatic philosophy in exploration of PPGP views; expressing views of PPGP sufferers upon the Pelvic Girdle Questionnaire (PGQ) and; being the first exploration of views upon PPGP by a male lead author. This combination of uniqueness provides a different dimension to previous published work, helps to support current literature whilst providing fresh insights into PPGP, and achieves the aim of this study, to gain an understanding of PPGP as experienced by women in the UK

#### **6.10.1 Symptoms of PPGP**

Regardless of when PPGP reaches its interventional need point, the physical symptoms and general impact of PPGP described by the women in this study are consistent with previous findings of Elden, Lundgren and Robertson (2013) and Stuge *et al.* (2011). Pain dominated the interviewee's descriptions, and impacts upon ADL's were a considerable issue. However, the researcher here believes that in comparison to the qualitative work of Elden, Lundgren and Robertson (2013), the physical symptoms in this study are described as being more intense. Also, the women in this study were shown the PGQ, developed by Stuge *et al.* (2011), and confirmed that it seemed applicable to them. This lends weight to its use in future studies of PPGP within the UK, such as the one in Chapter 7, whilst supporting the idea of asking functional based questions in relation to PPGP. Because the PGQ was developed in Scandinavia, based upon focus groups with Scandinavian women, these findings suggest PPGP is not cultural specific. Therefore, the data produced from this study went someway to influencing Chapter 7, as the women in the interviews here considered the PGQ as a representative outcome measure.

However, the PGQ would seem to not be an all-encompassing outcome measure for

PPGP, as there is no focus upon psychosocial issues. From the interviews conducted in this research, it is apparent that PPGP effects more than physical symptoms. This is a view held by Mogren, Winkvist and Dahlgren (2010), who found midwives believed PPGP affected pregnant women's mood, and Bjelland *et al.* (2012), who felt reducing emotional distress could lead to a reduction in post-partum PPGP rate's. One reason for this change in mood could be due to the impact PPGP has upon the ability to exercise, with Downs and Hausenblas (2004) finding that regular exercise helped to improve the mood of pregnant women.

However because researcher's found quality of life to be affected during pregnancy, for example with nausea (Broussard *et al.* 1998) and sleep disturbances (Ross *et al.* (2005), it could be that the mood symptoms were not as a direct result of PPGP. Despite this, Persson *et al.* (2013) go into some level of depth in their discussion of how pain during PPGP could influence the psychological wellness of the women. However, Persson *et al.* (2013) do not provide examples of a connection within their interviews between the pain and psychological distress, primarily making the links from other sources of literature. Although the findings in the study conducted here do not prove the existence between pain and emotional discomfort, there are specific examples provided within the 'The reality of PPGP theme' (see page 143), where the women considered that emotional distress was as a direct result of the PPGP pain. This helps to support Persson *et al.* (2013) and Elden, Lundgren and Robertson (2014a) suspicions of a connection, whilst remaining a unique piece of data to be reported upon.

#### **6.10.2 Information provision**

Factors such as amount of information provided about PPGP may also influence emo-

tional distress. Elden Lundgren and Robertson (2014) and Persson *et al.* (2013) highlighted that women made a point of suggesting that information around PPGP was lacking, with Engeset, Stuge and Fegran (2014) putting forward that information on PPGP was considered by the women in their study as of high importance. Fredriksen, Moland and Sunby (2008) go a step further in suggesting that providing information could help with coping and anxiety. This is suggestive in the study results displayed here, as several women commented on being able to deal with the symptoms better once they had full information surrounding their problem (see page 152), and supports Wellock and Crichton's (2007) conclusions surrounding the benefits of labeling.

Women in this study expressed levels of fear and anxiety when the pain appeared, and this could have been allayed by some degree if they had been armed with prior knowledge. The fact that women in this study all discussed using the internet as a source of information helps to validate the Fredriksen, Moland and Sunby (2008) study design of analysing blog entries; women used this as a source of information in their study. Indeed, the author's state that over 50% of Norwegian women used the internet to seek/give advice, and it is likely to be of similar if not higher rates for UK based women if this study is used as a marker for internet use.

### **6.10.3 Support network**

Given that the interviewee's in this study expressed a clear relief when a discussion had been held with a health professional, and that other studies such as Engeset, Stuge and Fegran (2014) also found support from health professionals to be of great importance, their role in PPGP management should not be underestimated. Also in agreement are Elden, Lundgren and Robertson (2013), who found women to appreciate doctors whom

had knowledge of PPGP. The researcher here found that information provision surrounding PPGP, for example providing a label, was mainly accredited to physiotherapists (see page 148), with the interviewee's highlighting the positive role they played, again in agreement with Wellock and Crichton (2007). However, the researcher is acutely aware that the participants in this study had been recruited from the physiotherapy team, were being interviewed in the physiotherapy department by a physiotherapist, and so the emphasis on the positive impact a physiotherapist has had could well have been influenced by this environment, despite stressing the confidentiality of the interview.

The importance of the support mechanism in this study also extends to family and friends, as was found in Elden, Lundgren and Robertson (2013). Persson *et al.* (2013) and Engeset, Stuge and Fegran (2014) noted the importance of receiving support from their partner and close family, and Elden, Lundgren and Robertson (2014b) found that co-inhabiting male partners were also aware of their importance in a supporting role. The women interviewed in the study within this chapter gave an emphasis upon this support, highlighting the role close family members, friends and a supportive partner had on their ability to manage their lives. One woman, who had ended a relationship with her partner, expressed how she felt this had made dealing with PPGP a lot harder, and this statement was supported by another interviewee who discussed an anxiety at the prospect of her husband being away from the household for several days (page 147). All women discussed the importance of their partner in the supporting of her pregnancy and dealing with PPGP, which suggests that the most important supportive role for the pregnant woman is that of her co inhabiting partner.

Another indication of how much support is valued was portrayed through how the PPGP sufferers felt they were perceived by others. Although this issue did not occupy huge

sections of the transcripts, the fact that some women felt they wouldn't be taken seriously by others, unless they had suffered PPGP, could add to the feelings of social isolation and lack of support.

#### **6.10.4 Expectations and treatment**

The expectations of women with PPGP has been something that has been missing from the published literature, and although it did not populate a major core to the data produced here, it was something which was discussed by several women, who indicated that they felt a lack of control over their PPGP, despite it being perceived as temporary (see page 145). Whether this is due to the lack of information about the condition, or just personal opinions, there is some lack of awareness of the potential of PPGP to develop into a chronic problem. The women interviewed here do however perceive that the PPGP will get worse as the pregnancy progresses, which is in agreement with findings in Kvorning et al (2004) and Da Silva *et al.* (2004), discussed in Chapter 3 (page 52). However, they also discussed having an end in sight, and therefore implicitly implying they can manage the condition as they feel it is temporary. This supports work by Engeset, Stuge and Fegran (2014), who also stated that the general outlook of PPGP was positive due to women's goals being to return to pre pregnancy function levels.

Although several quantitative research approaches have been adopted for the investigation of PPGP treatments, this study is the first to discuss what women's views are upon potential treatment options. The feelings around the use of painkillers reported by the women in this study came with a similar level of caution as the women who reported their views on medication in research by Nordeng, Koren and Einarson (2010). Although the women in this study did take painkillers, there was a feeling that this was only if absolutely necessary. Most of the women discussed using medication, but always within

the context of not wanting to do so. This reluctance to use pain medication could have bigger effects on their pain tolerance levels, but several mentioned that they had found other ways to manage their pain, as well as being open to the suggestion of other treatments such as acupuncture. Linking with “Support mechanisms most important in PPGP” theme, it is interesting that despite wanting to seek help for their condition and move away from medication, this was not to be at all costs (see page 149). Additionally, there was some indication that finance may also play a role in visiting hospital on a regular basis. This said, if a cultural reluctance exists regarding medication during pregnancy, it is perhaps pertinent to have alternative modes of treatment readily available for pregnant women. That way, there is a feeling of structured, patient-option based healthcare provision which in itself could be an important support mechanism. This advocates the execution of the study in Chapter 7, aiming to investigate the feasibility of KHA for PPGP research.

#### **6.10.5 Sick leave**

The lack of discussion around sick leave is worth noting, particularly since published qualitative work does frequently mention sick leave as a potential driver of PPGP (Persson *et al.* 2013; Dørheim, Bjorvatn and Eberhard-Gran, 2013). Despite the interviewer in this study directly asking about financial implications, seeking sick leave did not appear as a main driver for seeking medical attention for their PPGP. Therefore, based on this small study, it would seem that potential sick leave is not a main driver of PPGP in the North East of England.

Whilst Dørheim, Bjorvatn and Eberhard-Gran (2013) found that sick leave for PPGP was exclusively taken in the third trimester, suggesting that the issue becomes at its most troublesome at this point, and Kanakaris, Roberts and Giannoudis (2011) state that the



peak of PPGP is mainly within the third trimester, the interviews conducted within this study suggest that women rate their symptoms considerable enough to warrant medical intervention from the 2nd trimester. This has not been highlighted previously through a qualitative paradigm, and as such adds a level of originality. These findings may indicate that PPGP sufferers in the UK develop symptoms worth seeking medical attention earlier than their counterparts in other countries, though the lack of generalisability of this work prevents a more confident statement.

#### **6.10.6 Recommendations for future practice**

Going forward, this qualitative approach to exploring PPGP for UK women has highlighted area's that are in need of further consideration when designing future healthcare services. Currently, PPGP has not featured highly upon medical professionals' radar, evidenced by the lack of; published work such as text books that focus upon the condition; the distinct lack of knowledge in the profession about what it is (perhaps reflected in the lack of taught hours dedicated to it in undergraduate education); and lack of information that is given to women at the early stages of pregnancy. This is at odds with the findings of this study, and indeed the broader published literature, which points to PPGP having a significant impact upon women's' lives. From a UK perspective, there is currently no NICE guidelines on how to manage PPGP, which in itself demonstrates the distinct lack of understanding of its impact on pregnant women. Symptoms of PPGP seem to be largely unpredicted by women pre pregnancy, despite their impact.

The support of work colleagues, family, partner and friends is a strong thread throughout the interviews conducted here, but considering the constraints of the UK healthcare system, it is unlikely that any improved healthcare approach can encompass all of those

who can and do influence the pregnant woman. An ambitious suggestion could be to target the family unit during school age education, to try and improve awareness of how PPGP can impact on everyone. The pregnant women themselves stated that they did not expect the symptoms that they had developed, and that on some occasions, had been guilty of being dismissive of others when they had been in a similar position before they themselves had become pregnant.

Interviews with male partners of pregnant women by Elden, Lundgren and Robertson (2014b) also confirm a lack of preparation for PPGP, and were unaware of the physical and emotional strain it would have on them. Because the family unit in the UK is no longer characterised by sharing the same village as family and friends, perhaps the state has a responsibility to instil social responsibility for the future through school education. However, it is perhaps more realistic to suggest a group/family approach to pregnancy, their inclusion more strongly encouraged from the beginning of the pregnancy journey. If the information on PPGP could be made more easily accessible from early on, it may help reduce anxiety especially in the earlier stages, which in turn can help maintain those vital relationships which support the pregnant woman through her time with PPGP.

By providing pregnant women and their social support network with an easily accessible source of information, it could help with the fear that is associated with PPGP, in particular the early stages when the symptoms develop. Knowledge of PPGP could also help to support and empower the pregnant woman, which as highlighted previously, could help reduce vulnerability and give a better sense of PPGP in its totality, perhaps allowing adequate preparation for what is to come. All of the women in this study utilised the internet as a source of knowledge, with women trying to find reliable sources to refer to. It is therefore suggested to enhance the NHS website, to contain more detailed information.

Additionally, a comprehensive review of the information provided through the NHS website and information packs handed out on initial midwife appointments is needed. It could include advice on what PPGP is, the stages of PPGP and the help available potentially providing a welcome relief to not only the pregnant woman, but also a way to help manage busy caseloads of health professionals dealing with the plethora of pregnancy related issues.

Although this study consisted only of eight women, when taken into context of the wider literature base, the lack of information is clearly an issue, and one which women feel negatively impacts upon them. This said, the role of the health professional, and not just the midwife, cannot be understated. A compassionate, knowledgeable health professional was seen as an important support mechanism, empowering women to take back some control of their life and PPGP. It would therefore be unfeasible to suggest more thorough information was provided at the expense of healthcare visits.

#### **6.10.7 Potential future research**

By considering women's views, it allows for treatments to be tailored to suit what women with PPGP would most likely find acceptable, and from a researcher perspective, help the successful execution of any mixed methods study. As this study partially informs the study in Chapter 7, the exploration of views on treatment was seen as important as it may impact upon recruitment and retention. The constraints of the study design prevent the researcher here making any specific recommendations, however, it is clear that there is a range in what women would perceive as an acceptable treatment, whilst seemingly supporting the notion of caution around medication, put forward by Pham (2014) in Chapter 2. In addition, as the women in this study felt that the PGQ accurately reflected the main issues surrounding their PPGP, it was deemed an important outcome measure

to adopt in Chapter 7. Therefore, the findings of this study informed the research displayed within Chapter 7 through advocating an investigation of an intervention that was deemed acceptable to the participant, and supporting the use of the PGQ.

#### **6.10.8 Study strengths**

The researcher here believes there are several methodological strengths to this study. The semi-structured interviews produced rich data, which provided the basis to perform thematic analysis and subsequently broadening the researchers understanding of PPGP. This is likely due to the skill of the researcher at being able to ask the right questions at the right time, though admittedly the characteristics of the individuals involved likely helped with the provision of thick, data rich responses. The interview schedule, outlined in Appendix 10, demonstrates that the questions asked have helped to produce original takes upon PPGP, aiding comparison to existing literature whilst exploring area's that have perhaps been under reported to date. Similarly, it could be argued that because there were similar results to that of existing literature produced, it suggests that the researcher had asked questions and analysed the data that has a level of consistency with other published authors. However the counter argument to this is that it is possible themes generated here were influenced by the reporting of previous published literature, and not actually representative of what the women felt were the most important issues surrounding PPGP.

Further strengths lie in the explicit description of the data analysis process, including the data collection methods, as it helps with the dependability of the work produced; this is an issue that when absent is highlighted by a number of qualitative authors as a weakness (Patton, 2002), and therefore by attempting to address this through thorough description makes the reporting a strength. The data display within the results section also

helps the reader understand why certain categories led to themes, and what raw data was there to help support the claims made in each theme.

Finally, documenting reflexivity is considered a strength in qualitative research as it provides the reader with context of how the data may have been influenced, whilst also forcing the researcher to look at their own beliefs and attitudes to assess to what scale they are influencing the data analysis and synthesis stages (and perhaps even the data collection phase) (Carpenter and Suto, 2008). Reflexivity was given its own subsection within this chapter, and is discussed again briefly in section 6.9.10, making it clear to the reader of any potential influencing factors on the data analysis and synthesis stages.

#### **6.10.9 Study limitations**

Although the eight interviews here covered a wide demographic, and information gained from the seventh and eight interviews seemed to be covering the same responses as the previous six, there are limitations to this study that prevent the researcher from making more confident claims. To attempt to ensure credibility and authenticity, comparable to internal validity in quantitative work (Liamputtong 2009), the author could have adopted member checking, whereby the interviewee's read codes, categories and themes to try to ensure that the interpretation made by the researcher reflects the views expressed during the interviews (Liamputtong, 2009). Although, as will be reported upon in Chapter 7 of this PhD and was discussed earlier in this chapter with Wellock and Crichton (2007), doing follow up work with pregnant women can often result in attrition and therefore member checking can be difficult to execute.

In addition, further qualitative work could utilise focus groups, which could help to gain further consensus of the most pertinent points relating to PPGP, and expand upon some

of the findings that have been displayed in this study. This method allows the respondent to tell their own story, albeit in a group scenario, with the advantages of this approach being that more complex issues around the topic can be explored and clarified (Bowling and Ebrahim, 2005). This process of focus groups can also help to explore views and generate questions which might not be done in face-to-face interviews (Patton, 2002). Many group scenarios can prevent awkward silences, as found in face-to-face interviews at times, though this was not noted in this study. By utilising a focus group after the individual interviews, as seen in Mogren, Winkvist and Dahlgren (2010), it could have helped strengthen the trustworthiness of the themes produced as the women would have had chance to expand and clarify any pointers raised from the interviews (if member checking was done as part of this). It would have also provided an opportunity for triangulation if a focus group had been held with a different cohort but with very similar open ended questions posed. If similar results/emphasis had been found, the trustworthiness of the finding here would have been strengthened as it would mean that a different method had reached similar conclusions.

#### **6.10.10 Benefits to the researcher**

The researcher feels that this process has vastly enriched his understanding of the complex nature of pain and emotions, and how factors such as supportive people can make a huge difference on a pregnant women's ability to cope. Being a health professional, the researcher feels he has always had an empathetic nature, but the journey in which this work has led him on has immeasurably influenced the way he considers the wider considerations of what things matter to a pregnant women. On views of research, this has led the researcher to question the value of quantitative work as a standalone entity, as the amount of information and subsequent understanding the researcher now has from doing a selection of interviews has considerably improved his understanding of the

condition. Not surprisingly, the researcher feels the adoption of a mixed methods approach is something that is invaluable to understanding a condition, but also to ensure that the right questions are being asked in any quantitative approach involved in research. This would be supported by the MRC framework on complex interventions (Craig *et al.* 2008), as they too advocate using a number of methods to ensure thorough investigation.

#### **6.10.11 Chapter summary**

The fact that the majority of symptoms described in this study were very similar to previous studies of Scandinavian origin, suggests that PPGP behaves comparably in the UK. This study also highlights the similarity of issues that women face, mainly; disability impacting upon their ADL's; PPGP being a bio-psychosocial phenomenon; the dependency on support from healthcare workers, family and friends; the paucity of information available during the early stages of symptom development, and how this lack of information could be a cause of increase in anxiety. Taking these findings, combined with the literature reviewed in Chapter 2, highlights the need for a redefinition of PPGP. As it stands, the Vleeming *et al.* (2008) definition primarily focuses upon the physical symptoms, yet it is clear that there are a number of other factors that can be identifiable with PPGP, and therefore, define it. A more accurate definition is proposed within Chapter 8 on the back of the literature review in Chapter 2, findings presented within this chapter and results displayed within Chapter 7.

This study adds several original contributions to knowledge through; being the first UK based exploration of PPGP sufferers views; providing discussion around interviewee's expectations of treatment; being the first to adopt a pragmatic philosophy in exploration of PPGP views; expressing views of PPGP sufferers upon the PGQ and; being the first

exploration of views upon PPGP by a male lead author. However, this thesis is a mixed methods approach, and so the findings from this Chapter also support the method of Chapter 7.

Finally, Mogren, Winkvist and Dahlgren (2010) discovered that to help enable women with PPGP to have a close to normal life, acupuncture was thought to be the best method. In addition, studies such as Elden *et al.* (2008) suggest acupuncture could be effective for PPGP, but as this kind of study has not been done in the UK, and given that there are subtle differences between findings of this study and current published literature, it would seem a reasonable suggestion to investigate acupuncture effectiveness in the UK. In addition, a mixed methods study which focuses upon not only on pain but functional activity is warranted, as functional activities were what the pregnant women reported as being effected frequently. There have been no studies conducted as yet using a PGQ for PPGP, and any future studies that would look to use acupuncture for PPGP should consider using it. To remedy this, the researcher conducted a study into the use of KHA for PPGP, to investigate whether it is feasible to run on a larger scale.



## **Chapter 7**

### **Korean Hand Acupuncture for Pregnancy related Pelvic Girdle**

#### **Pain: A Feasibility Study**

##### **7.1 Background literature**

This chapter presents an investigation into the feasibility of the use of KHA for PPGP, in line with recommendations put forward by the MRC framework for complex interventions (Craig *et al.* 2008). Both quantitative and qualitative data were synthesised in order to produce recommendations for a future definitive RCT, with particular emphasis upon the practicality, acceptability and integrity of the research. This study produces an original contribution to research through being the first KHA study in English for a pregnancy related condition, the first to compare pKHA and npKHA in any English written study, and the first study in the UK to use the PGQ as an outcome measure for PPGP. Symptom changes for pain and ADL's are also measured, however, it is stressed that due to the limitations of feasibility testing, impact upon symptoms are noted as trends.

Core to the MRC framework for complex interventions, evaluation is a phased approach to feasibility testing (Craig *et al.* 2008). The NIHR (2015) define a feasibility study as a piece of research conducted before a main study, in order to answer the question "Can this study be done?" (NIHR, 2015). The MRC framework (Craig *et al.* 2008) highlight that evaluation of complex health interventions are often undermined by poor compliance, delivery of the intervention and recruitment and retention. In all of the randomised studies discussed in Chapter 3 surrounding acupuncture and PPGP, recruitment has not been identified as an issue. Erkdahl and Petersson (2010) recruited a total of 36 women over a 15 month period, Wang *et al.* (2009) achieved 159 completions within 35 months, and Elden *et al.* (2005) managed to recruit 321 women over a two year period, drawing

upon 27 different midwifery centres. However, attrition rates would seem to vary considerably.

Elden *et al.* (2005) had 38 drop outs in two years out of 225 recruited demonstrating a 14.4% in the acupuncture group. Ekdahl and Peterson (2010) reported eight drop outs from 40 recruited (20% drop out rate), Wang *et al.* (2009) had seven drop outs from 159 participants (4.5% rate) and Elden *et al.* (2008) reported attrition to be 7 (6%) out of 115 who enrolled onto the study. The MRC also stress the importance of highlighting the context in which the complex intervention is conducted to allow for appropriate evaluation and consideration if being implemented in other contexts (Craig *et al.* 2008). Therefore, the physiotherapists who work at the trust where the study was conducted were consulted on a number of issues, such as did not attend (DNA) rates, and will be discussed further in the results and discussion section of this chapter.

As discussed in Chapter 3 (see Table 3), a number of studies exist that have investigated acupuncture for PPGP. However, Clarkson, O'Mahony and Jones (2015) (see Appendix 12), and Gutke *et al.* (2015), as discussed on pages 47-59, consider that several studies (Wedenberg, Moen and Norling, 2000; Kvorning *et al.* 2004; Da Silva, 2004) are of poor quality, or have looked at effects over a short time frame (Wang *et al.* 2009).

Both Elden *et al.* (2005) and Elden *et al.* (2008) were considered more robust experiments, and thus lead a Cochrane review by Pennick and Liddle (2013) to put forward that acupuncture could be a useful intervention for PPGP. However, higher quality work is needed (Pennick and Liddle, 2013), and as aforementioned in Chapter 3, UK based research investigating acupuncture for PPGP is currently absent. In addition, the method of best practice has yet to be established, with Elden *et al.* (2005) and Elden *et al.*

(2008) opting for body acupuncture styles, whereas Wang *et al.* (2009) opted for a microsystem (auricular) approach. As outlined in Chapter 3 (page 81), the use of a microsystem, that does not require the participant to remain in a static position, may prove to be beneficial to PPGP sufferers, and may be a more accepted approach by those physiotherapists reluctant to use acupuncture. In a national cross sectional survey by Bishop *et al.* (2015), it was identified that over one third of physiotherapists who use acupuncture in pregnancy, use points on the hand; therefore, KHA would likely be acceptable to those who use hand acupoints. However, in order for any future definitive RCT which may follow this feasibility study, to be comparable to existing literature, the outcome measures adopted must be similar.

## **7.2 Outcome measures for feasibility testing with PPGP**

Collecting demographic data of the population being studied allows for assessment of homogeneity of the groups being investigated. This acts as a method of controlling for potential variables that could impact upon outcome (Teddle and Tashakkori, 2009). By gaining homogeneity, it allows for stronger internal validity of results gained, and the researcher can be more confident that outcome was as a result of the independent variable, in this case, the type of KHA administered (Bowling and Ebrahim, 2005). For example, Ekdahl and Petersson (2010) put forward that gestational age may have an impact upon treatment effect, and as it has been considered a potential influencing factor, should be considered when analysing data. Common throughout every study outlined in the literature review in Chapter 3 was the recording of maternal and gestational age and baseline scores of pain and other outcome measures being assessed. First trimester women are often excluded from research, consistent with the studies discussed earlier, likely because PPGP rarely presents itself within physiotherapy clinics at this time (Kanakaris, Roberts and Giannoudis, 2011), and three quarters of miscarriages happen

within the first trimester (NHS Choices, 2015). Demographics such as previous contraception (Bjelland *et al.* 2013; Björkland and Bergström, 2000; Damen *et al.* 2001; and Rost *et al.* 2006) and employment status have been measured in previous epidemiology studies (Fredriksen Moland and Sunby, 2008), with Bishop and Lewith (2008) putting forward that demographics such as age and work status may also influence reporting of outcomes in pain. However, for the study conducted by the researcher here, collecting demographic data also begins to produce characteristics of those who suffer with PPGP in the UK. This allows for comparison to larger studies conducted elsewhere, whilst beginning the task of understanding how PPGP presents itself within the UK. Therefore, the baseline demographics of maternal and gestational age, gestation on enrolment, amount of exercise per week, pain intensity (via NRS) and ADL's (via PGQ) were collected for the study outlined in the method section of this chapter.

Further impacting variables of believability and credibility were discussed in Chapter 3 (page 76), with those studies measuring them (Wang *et al.* 2009; Elden *et al.* 2008) able to report on whether they were a potential influencing factor on outcome. Chapter 5 outlined the need to continue to observe believability of the npKHA and pKHA interventions, and so although the outcome measure adopted in Chapter 5 is not validated, in order to compare to the results found, it was included in the study outlined in this chapter (displayed in Appendix 19). Additionally, Bishop and Lewith (2008) highlighted that positive beliefs lead to better outcomes for pain, which acknowledges that treatment credibility could be a potential impacting variable for PPGP. The incorporation of a credibility scale (Appendix 20), as used by Elden *et al.* (2008), was included in the study outlined below, providing insight into pKHA and npKHA credibility as well as the study protocol acceptability. The scale is made up of four Likert type items, each with five options, ranging from strongly disagree to strongly agree (see Appendix 20).

As discussed in Chapter 3, pain and functional activity are the two outcomes of treatment that are most frequently assessed. Wu *et al.* (2004) found that pain in PPGP was most commonly reported between 50mm and 60mm on a VAS, but with the upper quartile of women reporting it as 90mm, suggesting 25% of women affected by PPGP suffer with extreme pain. The VAS or NRS are the most commonly used outcome measures (Ek Dahl and Petersson 2010; Elden *et al.* 2005; Elden *et al.* 2008; Wang *et al.* 2009) with both considered to have excellent test retest, construct validity and have a high correlation with one another (Hawker *et al.* 2011). In particular, the NRS has an excellent ability to detect change with a reduction of 2 points considered clinically important (Hawker *et al.* 2011). The use of the NRS is therefore an appropriate outcome measure to assess pain, and has been included within this feasibility study to partially measure KHA effectiveness. However, unlike the NRS, ADL outcome measurement use in PPGP studies carries a level of discrepancy. Some authors opted for measuring impact on individual Likert type items (Da Silva *et al.*, 2004; Kvorning *et al.* 2004), whilst others used the DRI (Wedenberg, Moen and Norling, 2000; Elden *et al.* 2005; Elden *et al.* 2008). Although the DRI is considered a valid and reliable outcome measure (Grotle *et al.* 2012), it has not been validated for PPGP use, and thus raises questions surrounding its validity with this population. The PGQ is a PPGP specific outcome measure developed by Stuge *et al.* (2011). Further, participants in the qualitative study presented in Chapter 6 indicated the PGQ to be appropriate for measuring their symptoms.

An example of the PGQ used in practice can be observed in Wild (2014), in their case study publication. A VAS and the PGQ were used to measure effectiveness of acupuncture in combination with standard physiotherapy, finding at least eight of the items to demonstrate an improvement after six sessions. In addition, Clinton *et al.* (2014) produced a set of guidelines for the American Physical Therapy Association for PPGP, and

also suggested using the PGQ as a potential outcome measure. Flack *et al.* (2015) used a VAS for over last 24 hours and last week, and although their data collection preceded the publication of the PGQ, they would advocate its use if it had been available. Further to this, the PGQ has been used to test for convergent validity of two timed up and go tests (Evensen, Kvale and Braekken, 2015), which lends further credibility to its use in practice, with Evensen, Kvale and Braekken (2015) going on to recommend that the PGQ should be used when assessing PPGP. Finally, Verstraete, Vanderstraeten, and Parewijck (2013) advocate the use of the PGQ in their paper on a proposal for a clinical pathway for dealing with PPGP. On the basis of these studies and the findings of the study conducted in with stakeholders in Chapter 6, the PGQ was therefore adopted in the study outlined in this chapter.

Although for this feasibility study a specific outcome measure was not adopted to measure psychosocial state, women were asked to report their general wellbeing between sessions. Elden *et al.* (2008) were the only authors to measure wellbeing via the EQ-5D, finding that it was non-significant ( $p=0.511$ ). By collecting qualitative data from participants rather than through a formal outcome measure, the researcher here intended to discover whether general wellbeing effects were noted, to decipher whether it should be measured in a definitive RCT. This qualitative data also served to provide insight into why participants continued with the study and their views on the study as a whole, captured using qualitative comments (Appendix 13) as well as completion of an end of study questionnaire (displayed in Appendix 16).

### **7.3 Informing the delivery method**

Prior to submitting this study for ethical approval, there was a prolonged consultation

with women's health physiotherapists in order to ensure that the study could be conducted at the hospital identified. The physiotherapists were consulted on the demographics of patients that they see, what their usual referral numbers were (over 100 per month), numbers of people who DNA for treatment (50% for ante natal issues) and what the usual process of PPGP diagnosis and treatment was. They highlighted difficulty in treating PPGP due to the lack of available treatment options and time constraints, with the usual care approach being one session to provide diagnosis, information and advice. Patients usually received manual therapy and hydrotherapy, or walking aids, if the condition progressed. This consultation period lasted for over one year and helped to shape the whole PhD study, and was essential in order to assess whether it would be the most appropriate hospital to deliver the study. Drawing upon the range of experiences and opinions of the four physiotherapists was an important part of the method underpinning this chapter, and is supported by the MRC framework as they advocate stakeholder involvement for any complex intervention development.

The findings from the pKHA vs. npKHA study in Chapter 5 were implemented into the delivery of KHA described below. As the two methods of KHA appeared to be believable, and produced no adverse events, it seemed that the approaches were adequate to be used in this study. However, the qualitative data produced from Chapter 5 were considered, and therefore influenced some methodological design for this study. The aspects of the npKHA that remained from Chapter 5 were the replication of needle removal, as one participant in the npKHA group had noted this as a reason why they had believed they had pKHA. Additions to the method outlined in Chapter 5 for the non-penetrating approach were to include rustling of acupuncture needle packaging so to replicate what would be heard in an acupuncture treatment, and to ask participants to not move their

hands. It was also stressed before beginning the study that either group could experience side effects such as red marks and tingling sensation, and that both groups may or may not have a change in symptoms.

Chapter 6's results influenced the design of the study outlined below in several other ways. The use of the PGQ was included as participants in the interviews conducted in the Chapter 6 study considered it to be reflective of the issues that they suffer with during PPGP. One comment was made that some of the items on the PGQ could be attributable to pregnancy in general, so a note was made at the top of the PGQ, as well as verbal instruction, that each item was within the context of PPGP. If they were unable to do a specific task as a result of a co morbidity or general pregnancy, they were to record N/A in the box provided. A thorough explanation and information leaflet (Appendix 16) was given to all participants prior to enrolment onto the study, as information provision was considered valuable in the findings of Chapter 6. Participants also had continued support from the physiotherapy team if they wished to have further advice, as is normal with standard practice at the hospital, and in keeping with the importance that the interviewees expressed in Chapter 6 regarding supportive health professionals.

Given that there were some concerns raised by interviewee's in Chapter 6 around attending numerous sessions over a period of time, the study allowed flexibility in frequency of delivery, as long as six sessions were completed with an eight week time frame. The amount of sessions also reflected usual practice of acupuncture within the hospital, and as discussed in Chapter 3, would be considered usual practice by some UK physiotherapists (Bishop *et al.* 2015). Women were included from the second trimester onwards, as although reviews by Kanakaris, Roberts and Giannoudis (2011) state the peak of issues arise in 3rd trimester, the women involved in Chapter 6 were all



in the 2nd trimester and seeking an intervention to help with PPGP. Within the discussion pre enrolment, women almost always asked about the safety element of KHA, and so results from a recent safety systematic review (Clarkson, O'Mahoney and Jones, 2015) were discussed.

## **7.4 Aim**

To develop and implement a study investigating the practicalities of delivering KHA for PPGP, through analysing the following:

- i Number of eligible patients/willingness of participants to be randomised;
- ii Study attrition/the practicality of delivering the intervention in the proposed setting;
- iii Willingness of clinicians to recruit participants;
- iv Time needed to collect and analyse data;
- v Suitability of the outcome measures used;
- vi Acceptability of pKHA and npKHA;
- vii Record of adverse events (Appendix 2);
- viii Physiotherapy staff views on the study, and;
- ix Making between and within group comparisons on any emerging trends within the data

## **7.5 Method**

### **7.5.1 Study design**

This was a three armed randomised controlled feasibility study, including a control group (standard physiotherapy, SP)), a SP plus npKHA group, and a SP plus pKHA group

(comparable to Wang *et al.* (2009)). For standard physiotherapy, all participants were given stability exercises and advice. At the physiotherapists discretion participants were offered hydrotherapy, a pelvic belt, walking aids and/or manual therapy. The study design was later modified to include only the SP plus npKHA and SP plus pKHA due to recruitment and randomisation issues (see p.187).

### **7.5.2 Ethics**

Approval was sought and granted by the Faculty of Health and Life Sciences Research Ethics Review Panel, 24th October, 2013, ref. number: RE-HLS-12-130701-51d1815248c3f. It was then passed for ethical approval via Newcastle and North Tyne-side 1 NRES Committee reference number 14/NE/0060, 7th April 2014 (see Appendix 24) before subsequent local hospital R and D approval (Appendix 25).

### **7.5.3 Recruitment (Women's health Physiotherapy Department)**

The potential participant attended their usual physiotherapy appointment, and if they met the inclusion criteria for the study, was given the participant information sheet (Appendix 16). The participant was considered to have PPGP if they fitted Vleeming *et al.*'s (2008) definition, and positive tests on P4, ASLR, pelvis palpation and FABERs. Each potential participant was given standard physiotherapy by the physiotherapist, and if the individual was interested in the study, gave consent for the contact details to be left for the researcher to contact them, or alternatively could contact the researcher directly. Potential participants were contacted by telephone. Those who did not wish to join the study were asked their reasons, and those who did not answer the phone were telephoned twice with a message left each time. If no response was received after the second attempt to contact, the individual was considered to have declined the opportunity. On attending the enrolment session the PhD student, who was the Chief Investigator, explained the study

along with risks and benefits, drawing upon previous research identified by Clarkson, O'Mahoney and Jones (2015), with potential participants encouraged to ask questions. Many attended with a chaperone, which was encouraged. Consent was confirmed through signing the form displayed in Appendix 17.

#### **7.5.4 Sample size**

The sample size was guided by Sim and Lewis (2012), who recommended 60 participants in a pilot study to allow for 90% confidence level when attempting to carry out a power calculation for a definitive RCT. The aim was to recruit 20 women for each of the three arms of the study. On numerous discussions with physiotherapy staff at the women's health department, the target of 60 seemed achievable within 12 months (therefore a 12 month timescale was set). On the last audit conducted by the hospital physiotherapy staff, approximately 100 patients with PPGP per month had been assessed and treated. The study cut off point was originally set at 60 completing participants or 12 months, whichever was first. However, due to factors discussed later in this chapter, the decision was made to remove the control only arm from the study in the first three months and thus became a two-armed study (comparable to Elden *et al.* 2008). Therefore, randomisation to the study after October 2014 was to the npKHA or pKHA group, with 20 women recruited to each. There was also a study extension granted by NRES, with the new completion date moved from April 2015 to November 2015 (see Appendix 21).

#### **7.5.5 Inclusion criteria**

The Inclusion criteria for this was:

- Ability to provide informed consent
- Diagnosed by physiotherapist as having PPGP

- Absence of red flags
- 2nd-3rd trimester of pregnancy (as per studies outlined in Table 3)
- Single pregnancy
- Any age/ethnicity/profession
- Not contraindicated to physiotherapy or acupuncture

#### **7.5.6 Outcome measures**

##### Primary outcome measures adopted:

- Pain intensity: NRS at time of completing (Appendix 19)  
NRS for average of last week (Appendix 19)

##### Secondary outcome measures

- General demographics (Appendix 18)
- Needle penetration believability (Appendix 19)
- Credibility Scale (Appendix 20)
- Activities of Daily Living: PGQ (Appendix 1)
- Participants' experience of the intervention

(See 7.5.12 Data analysis for further detail on outcome measures)

#### **7.5.7 Location**

The study was conducted at the Women's Health Physiotherapy Clinic in the North East of England.

#### **7.5.8 Procedure**

The procedure for the pKHA and npKHA was previously described in the procedure section in Chapter 5. Both approaches were repeated on six separate occasions within an 8-

week period, with a material blindfold replacing the blindfold goggles. There were no restrictions upon frequency of sessions. This was to aid recruitment and retention, and to replicate standard acupuncture practice. Once the intervention had been administered, the researcher left the room, whilst staying close by in case of an adverse event. Maintaining very similar researcher interaction for all participants reduces the impact this may have as an impacting variable, as outlined by Kaptchuk *et al.* (2008) in Chapter 3.

All participants were informed of the potential benefits, as this acts not only as an ethical imperative, but also as something which Kong *et al.* (2006), discussed in Chapter 3, proposed to be potentially beneficial to analgesia. The potential participant completed demographic data (Appendix 18), two NRS (Appendix 19) and the PGQ (Appendix 1) prior to being blindfolded, with the needle penetration believability outcome measure (Appendix 19) and the credibility scale (Appendix 20) given after receiving the intervention. The participant repeated the outcome measures at the third session and final session (see Table 14). The CI delivered all interventions. Throughout the study, the CI recorded information that pertained to the feasibility of the study in line with the objectives i – ix, as outlined on p.177. Recruiting physiotherapist's views on the study data were collected through a post-study discussion, with notes made by the CI of the comments made.

**Table 14 Feasibility data collection overview**

<b>pKHA/npKHA sessions</b>	<b>data gathered</b>	<b>session duration</b>
<b>Pre enrolment</b>	Patient Information leaflet (Appendix 16) given to potential participant	N/A
<b>session 1</b>	Consent gained NRS at time of completing NRS for average of last week General demographics Needle penetration believability Credibility Scale PGQ Qualitative data	45 minutes
<b>session 2</b>	Qualitative data	30 minutes
<b>session 3</b>	NRS at time of completing NRS for average of last week Needle penetration believability Credibility Scale PGQ Qualitative data	40 minutes
<b>session 4</b>	Qualitative data	30 minutes
<b>session 5</b>	Qualitative data	30 minutes
<b>session 6</b>	NRS at time of completing NRS for average of last week Needle penetration believability Credibility Scale PGQ Qualitative data End of study questionnaire	45 minutes

### **7.5.9 Adverse event reporting**

As put forward by Clarkson, O'Mahoney and Jones (2015), adverse events were recorded.

Participants were asked on returning to clinic, for every session, whether they had experienced anything untoward, beneficial or otherwise.

#### **7.5.10 Randomisation**

Simple randomisation was conducted, whereby a University member of staff, who was not directly involved in the study, provided an allocation code to 150 envelopes. In order to achieve allocation concealment, all randomisation, concealing of envelopes containing a group allocation code, and numbering of each pack was performed by a University member of staff not involved in data collection or analysis. Each participant, on enrolment to the study, was allocated the numbered pack which was next in line, all packs being stored in a locked cabinet. The group allocation was concealed within each pack and not revealed until the participant attended the session. When the pack contained SP allocation, the next pack was selected until finding a pack that contained randomisation to pKHA or npKHA.

The CI was blinded to the sequence. On collection of completed outcome measures every two weeks, the pre-sealed envelopes were checked by the CI for tampering. Completed outcome measures were stored in a locked filing cabinet within the women's health physiotherapy department, and transported by the CI via a locked brief case to Northumbria University, where they were stored in a locked filing cabinet in room G207, Coach Lane Campus, Northumbria University. Once data had been inputted into a password protected computer, the paper outcome measures were destroyed.

#### **7.5.11 Blinding**

Attempts to prevent unblinding were via a blindfold for the participant and any accompanying chaperone. The CI was blinded to the outcome measure completion by asking participants to complete the outcome measures and insert into an envelope which was subsequently sealed. This was an attempt to reduce researcher bias potentially influencing data. All data were anonymised on input to the electronic database, with participants advised that they could contact the CI after October 1st, 2017, if they wished to find out the

results of the overall study.

#### **7.5.12 Data analysis**

The NRS is an 11-point scale ranging from zero to ten, and is considered to produce ordinal data (Price, Staud and Robinson, 2012). The PGQ measures the extent of how much PPGP affects daily activities, and is made up of 25 Likert type items, each ranging from zero (not at all) to three (to a large extent). The score range is from zero to 75. The credibility Likert scale (Appendix 20) has four, 5-point Likert items which range from strongly disagree (1) to strongly agree (5). The potential score range is from four to 20. The believability Likert item, discussed in Chapter 5, is a scale ranging from definitely true KHA as 1, through to definitely not true KHA as 5. Measurements took place three times for each outcome measure; at baseline, midpoint and final point. The PGQ, credibility scale and believability Likert scale were all considered ordinal data, and as with the NRS, were analysed using a Friedman's ANOVA and a two-tailed exact significance test for within group comparisons. *Post hoc* analysis was also conducted through Wilcoxon Signed Rank Tests being conducted for each time point comparison, with Bonferroni correction executed to correct the significance level. A Mann Whitney U test with two-tailed exact significance was conducted for between groups at each data collection point.

For the demographic data produced, maternal age and gestation at PPGP onset were found to be normally distributed (see Appendix 23), and therefore analysed using independent t-tests. Gestation on enrolment and amount of exercise per week were analysed through the Mann Whitney U test, as the data were not normally distributed (see Appendix 23). All dropouts were included in data analysis as this is in line with the intention to treat principle (Dziura *et al.* 2013), as drop out data should not be deleted (Dziura *et al.* 2013). Dropouts or missing data were assigned the score previously given, as was performed by



Elden *et al.* (2008). A Little's Missing Completely At Random (MCAR) test was conducted to test for significance. If the data presented were below  $p=0.05$  it would be considered Missing At Random (MAR) or Missing Not At Random (MNAR). If it was above it would be considered Missing Completely At Random (MCAR). If the data are MCAR, then dropouts are not related to other data items, meaning dropouts would be purely random.

The qualitative data that were recorded in questions 4-5 on Appendix 19, Appendix 15, and comments made during the study (Appendices 13 and 14), were analysed using content analysis. Qualitative data collected from the recruiting physiotherapists were also analysed through content analysis.

#### **7.5.13 Costs**

Needles, blindfolds, sharps bins, sticky plasters, plastic toothpicks and all associated paperwork were paid for by the CI. The study was unfunded.

#### **7.5.14 Timescale**

It was initially envisaged that data collection for the study in this chapter would take approximately twelve months, however the CI requested a six-month extension, which was granted (details of this explained in the results section, NRES letter in Appendix 21). The data collection for this phase lasted 15 months.

## 7.6 Results

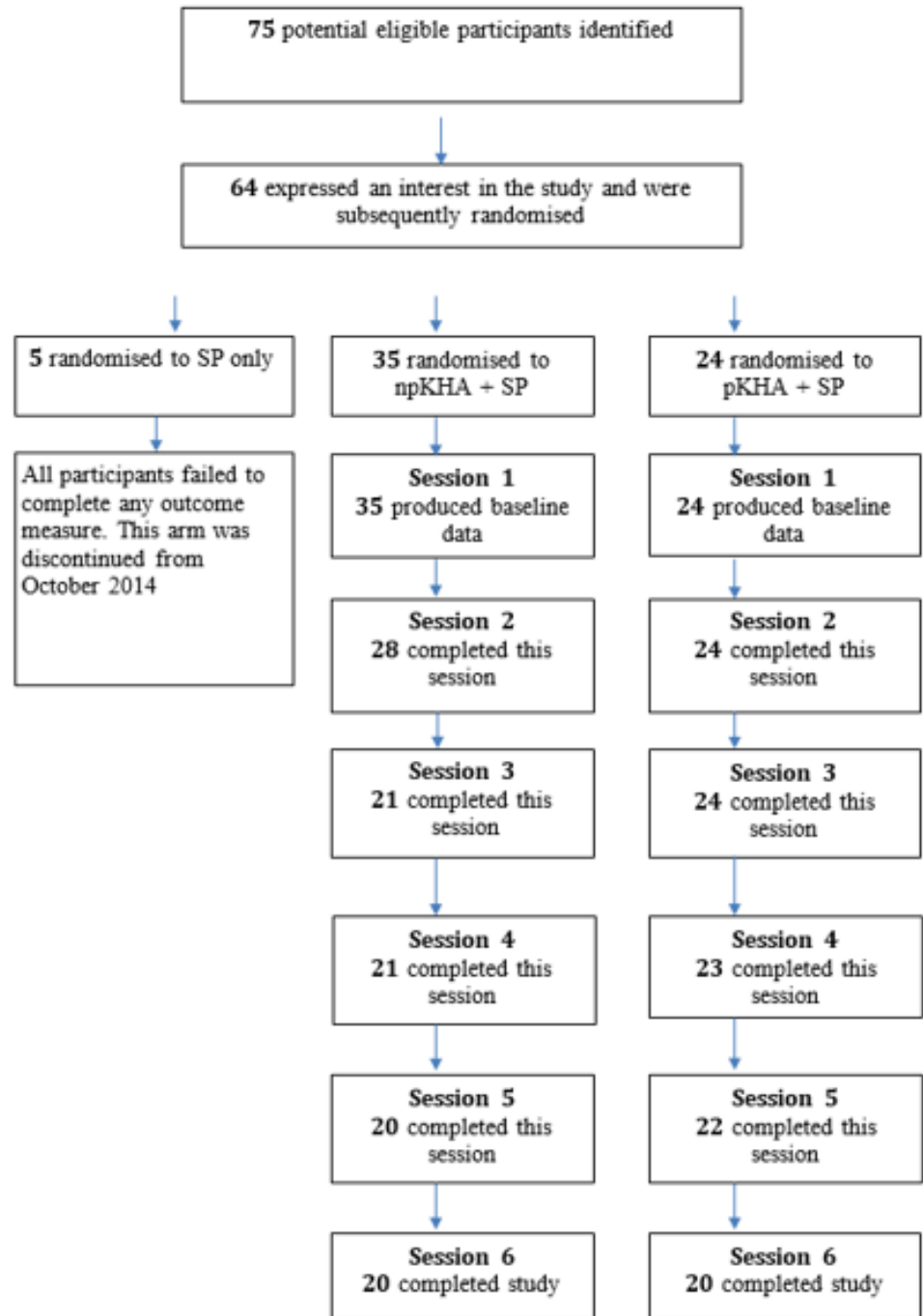


Figure 1 - recruitment and retention flow chart

### **7.6.1 Number of eligible participants/willingness of participants to be randomised**

Out of 75 potential participants identified as eligible to join the study, 85% (64 women) gave consent, with 59 providing baseline information. Those who chose not to enrol (n=11) gave a variety of reasons, such as:

- Hospital too difficult to get to (n=4);
- Too difficult to park (n=2);
- Do not want to be randomised to no treatment (n=1);
- Do not want to be randomised to an ineffective treatment (n=1);
- Felt co existing co morbidities would prevent from regular attendance (n=1);
- Unable to attend due to childcare issues (n=1);
- Felt the potential adverse events were not worth the potential benefits (n=1)

Five women were randomised to the control group, all of whom did not complete any of the outcome measures. All women expressed that they did not wish to be involved in the study if only involved in the control group. Following discussion with the CI's principal supervisor and consultation with a member of a local NRES committee, it was considered disadvantageous to the study completion if the control group was maintained. In addition, a previous study by Elden *et al.* (2008) had adopted a two-arm design, so the revised two-arm study would remain comparable to existing literature. Therefore, the control group was removed.

### **7.6.2 Study attrition/the practicality of delivering the intervention(s) in the proposed setting**

Figure 1 outlines attrition and when it occurred. To ensure that dropouts were not due to

a severe adverse event, hospital admission records were checked by the recruiting physiotherapists. No serious adverse events were noted. Nineteen dropouts were recorded, and the reasons given for not completing the full quota of six sessions were:

- Increase in symptoms (n=2 npKHA, n=1 pKHA)
- Could not be contacted (n=7 npKHA, n=1 pKHA)
- Did not feel that they could continue with regular appointments (n=2 npKHA)
- Ongoing health problems (n=1 npKHA)
- Gave birth (n=1 pKHA, n=1 npKHA)
- Arising family issues (n=1 pKHA, n=2 npKHA)

There were four dropouts in the pKHA group; one due to increase in symptoms, one gave birth, one quoted arising family issues, and one could not be contacted. Two attended four sessions, one attended three and the other five sessions. There were 15 dropouts within the non-penetrating group, seven of whom were not contactable to find out the reason. Two participants dropped out due to increase in symptoms, two due to arising family issues, one had given birth, one dropped out because of ongoing health problems preventing regular attendance, and two because they could not continue with regular appointments.

### **7.6.3 Willingness of clinicians to identify potential participants**

Four physiotherapists were based in women's health. Within the first three months of the study running, the CI recognised that the amount of potential participants being identified was lower than expected. The CI therefore chaired a meeting with the identifying physiotherapists. It was reported that the study was not a primary focus and therefore the physiotherapists were forgetting to ask patients whether they would be interested in the study. To combat this, posters were put up in the waiting area and each individual clinic

room, to remind the physiotherapist to ask about the study, as well as making patients aware that the study existed. The PIS forms were re-located to be in eyeshot of the physiotherapist to act as a reminder of the study, and the CI sent weekly update emails of recruitment rates to keep the study in memory. These tactics appeared to work, as from the fourth month onwards, recruitment and completion rates improved.

#### **7.6.4 Time needed to collect data**

The original time allocation of 12 months to complete the data collection was ambitious and ultimately proved to be an inappropriate time frame to reach the sample size required. The original time frame was based upon estimations of PPGP sufferers given by the department physiotherapists, which turned out to be an overestimate. In addition, recruitment in the first three months was much lower than expected. The CI recognised three months into the feasibility study that this would not be a realistic timeframe to recruit the total number of participants needed, given the recruitment rate to that point, and so requested from NRES a six month extension, which was granted (see letter Appendix 21). In addition, the CI was only able to conduct the study on a part time basis, primarily as they were a full time employee at a University and were only able to attend the clinic when it was available. Clinic availability was usually two and a half days per week, though this at times was less, depending on staffing levels. Due to the flexible nature of the study design, 103 clinic days were needed to recruit and complete 40 women to the study.

#### **7.6.5 Suitability of the outcome measures used**

On the general demographics form, several women did not understand the word gestation and/or know what PPGP stood for. The PGQ was occasionally not completed in full as participants forgot to check the back of the page, and so required a prompt from the

CI to complete. One wheelchair user found the PGQ to be inappropriate in several instances as she rarely participated in many of the tasks. The NRS for 'pain at this present time' was interpreted by some as at that moment, others as over the last 24 hours. With PPGP being aggravated by movement and relieved by rest, this could have impacted upon results given. The final question on the feasibility outcome measure (Appendix 19) was obsolete as the session number dictated how many times they had received KHA.

#### **7.6.6 Acceptability of pKHA and npKHA**

Table 15 demonstrates the end of study questionnaire results in percentage form for the pKHA and npKHA groups respectively. Nineteen out of the 20 women in the pKHA group and 17 of the 20 women in the npKHA group completed the questionnaire. Of those that completed it, all but one person completed it in full. Most people in both groups (pKHA 68%, npKHA 64%) enrolled onto the study to help with symptoms, with three participants enrolling because it was recommended and three participants enrolling to help with research, in both groups. Symptom relief was the reason why most women continued with the study for both groups, though 18% recorded a hope that it would help in the npKHA group, suggesting they had not had relief at that point. Both groups had one person that stated that they wanted to give enough time for treatment to work. Two women in the pKHA group continued with treatment as they were gaining benefits to relaxation, something which was not reported upon in the npKHA group.

All but one woman would seek pKHA again, whereas two would definitely not look to use npKHA in the future, with both groups having one person record probably. All women thought the study information was accurate and that no additional information was needed. One person in each group stated that the hospital location was inconvenient, with one from the pKHA suggesting a different position for her to lie in and one from the

npKHA group suggesting time from work proved difficult. The pKHA group had two women suggest the study be extended so they could receive pKHA for longer, with two women in the npKHA group making separate suggestions of including music to the treatment time, and a suggestion of running the study at a GP practice.

**Table 15 - End of study questionnaire results**

	<b>pKHA</b>	<b>npKHA</b>
<b>Why enrol onto study?</b>	To gain improvement to symptoms – 68% (n=13) It was recommended – 16% (n=3) To be involved in research – 16% (n=3)	To gain improvement to symptoms – 64% (n=11) It was recommended – 18% (n=3) To be involved in research – 18% (n=3)
<b>Why continue?</b>	Symptom relief – 60% (n=12) Relaxation – 10% (n=2) Commitment to study – 6% (n=1) Easy access – 6% (n=1) Help others – 6% (n=1) Time for treatment to work – 6% (n=1) Previous acupuncture worked – 6% (n=1)	Symptom relief – 52% (n=9) Hope it would help– 18% (n=3) Help others through research – 18% (n=3) No comment – 6%(n=1) Give time for treatment to work – 6% (n=1)
<b>Would you seek it again?</b>	Yes – 94% (n=18) Possibly – 6% (n=1)	Yes – 82% (n=14) No – 12% (n=2) Possibly – 6% (n=1)
<b>Anything inconvenient??</b>	No – 88% (n=17) Additional trips to hospital – 6% (n=1) Position during treatment – 6% (n=1)	No – 88% (n=15) Fit in with work – 6% (n=1) Hospital location – 6% (n=1)
<b>Accurate PIS?</b>	Yes- 100% (n=19)	Yes- 100% (n=17)
<b>Additional information needed?</b>	No -100% (n=19)	No -100% (n=17)
<b>Recommendations for a future study?</b>	Nothing – 78% (n=15) Give more treatments – 10% (n=2) Further promotion of KHA 6% (n=1) Change wording of PGQ – 6% (n=1)	Nothing – 88% (n=15) Music during treatment 6% (n=1) Conduct at GP practice – 6% (n=1)



### 7.6.7 Recording of adverse events

Table 16 displays the number of adverse events, with Appendix 22 providing information on the types of adverse events experienced. In the pKHA group, almost all women experienced an adverse event, with 56% of sessions causing an adverse event. One woman experienced three separate adverse events (acupoint bleeding, bruising and nausea), two women experienced two different adverse events (one bled and bruised, the other bled and itchiness). In the npKHA group, one adverse event of increase in symptoms, was noted in one woman immediately after two of her sessions, and she subsequently dropped out of the study. All adverse events were minor and did not require medical attention.

**Table 16 - Reporting of adverse events**

amount of women included in sample	total amount of sessions of penetrating KHA	amount of women effected by at least one adverse event	total amount of transient adverse events that occurred (% of sessions an event occurred in)	total amount of serious adverse events
24 (4 being drop outs)	136	23	76 (56%)	0 (zero)
35 (15 being drop outs)	145	1	2 (1.3%)	0 (zero)

### 7.6.8 Physiotherapy staff views on study

After the data collection had been concluded, and initial data analysis had begun, the CI discussed the study with all four recruiter physiotherapists. The physiotherapists were interested in the continued attendance in the study, as it was higher than usually observed in the clinic. The group speculated that this may indicate the importance of patient therapist contact, citing several examples from their own clinical practice whereby

some women who had presented with severe PPGP had been dramatically improved after just one session. They also expressed that no change to symptoms compared to baseline would be considered an improvement for PPGP, in their experience, as they would expect pain and movement dysfunction to continue to worsen as the pregnancy progressed.

No concerns were expressed surrounding their involvement in recruitment, and they expressed some level of surprise that there had not been more reports of unblinding. One physiotherapist stated that one of the patients who she had referred and subsequently dropped out after one session, had told her that she had looked under her blindfold whilst being administered the non-penetrating KHA, and therefore decided to not continue. She had failed to respond to the CI's attempt to be contacted surrounding her DNA, and thus provided some insight into why at least one person dropped out of the study.

#### **7.6.9 Making between and within group comparisons on any emerging trends within the data**

A little's MCAR test was conducted on all data, with a significance found to be  $p=0.701$ . This, therefore, states that missing data is Missing Completely At Random, and, therefore, no trends were noted in those who had missing data to those who did not.

#### **7.6.10 General demographics**

Data for age and gestation of PPGP onset was considered to have a normal distribution (see Appendix 23), and as the data was interval, an independent samples t test was used for comparing between the two groups. Table 17 demonstrates there were no statistically significant differences for age ( $t=0.649$ ,  $df=57$ ,  $p=0.931$ ) and gestation of PPGP

onset ( $t=0.221$ ,  $df=57$ ,  $p=0.881$ ). No significant differences were noted for gestation on enrolment to the study ( $z=-0.958$ ,  $df=59$ ,  $p=0.896$ ), amount of exercise per week ( $z=-0.0894$ ,  $df=59$ ,  $p=0.511$ ), baseline NRS at present ( $z=-0.674$ ,  $df=59$ ,  $p=0.506$ ) and NRS for average over the last week ( $z=-1.312$ ,  $df=59$ ,  $p=0.192$ ). Additionally, the PGQ data was also found to be no different between the two groups ( $z=-0.610$ ,  $df=59$ ,  $p=0.547$ ) at baseline.

The mean maternal ages for the groups were 31 years old for the pKHA group and 30 for the npKHA group. Hours of exercise per week were also very similar between the groups, at one hour for the pKHA group and two hours for the npKHA group. Average gestation at enrolment into the study was 29 weeks for both groups, with gestation of PPGP onset recorded as 19 weeks for the pKHA and 18 for npKHA. Table 18 demonstrates that there were no differences between the two groups for the remaining demographic data of marital status, occupation, education or type of contraception

**Table 17 - Demographic data - comparisons between groups**

Baseline data measured	Mean/Median		IQR		Test statistic (z/t)	df	Statistical Significance
	pKHA	npKHA	pKHA	npKHA			
<b>Age*</b>	31	30	27-34	27-35	0.649	57	p=0.931
<b>Gestation on enrolment**</b>	29 (3rd trimester)	29 (3rd trimester)	22-31	23-32	-0.958	59	p=0.343
<b>Gestation of PPGP onset*</b>	19	18	15-24	14-23	0.221	57	p=0.881
<b>Amount of hours of exercise per week**</b>	1	2	0-3	0-3	-0.658	59	p=0.511
<b>NRS for current pain level (/10)**</b>	5	5	3-6	5-7	-0.674	59	p=0.506
<b>NRS for pain over last week (/10)**</b>	6	7	4-7	6-8	-1.312	59	p=0.192
<b>PGQ score (/75)**</b>	41	42	29-52	33-54	-0.610	59	p=0.547

\*Statistical test adopted: Independent t-test

\*\* Statistical test adopted: Mann Whitney U

**Table 18 - Nominal Demographic Data most commonly recorded**

	Marital Status	Occupation	Education	Contraception
<b>pKHA</b>	Married	Sedentary	Degree	Not on contraceptive pill
<b>npKHA</b>	Married	Sedentary	Degree	Not on contraceptive pill

### 7.6.11 Credibility and Believability of KHA

Table 19 shows that for within group comparisons, there was no overall difference in believability for pKHA ( $\chi^2=2.8$ ,  $df=2$ ,  $p=0.350$ ) or npKHA ( $\chi^2=1.217$ ,  $df=2$ ,  $p=0.575$ ). Table 20 demonstrates that there was no difference within group for credibility when using the Friedman's test for pKHA ( $\chi^2=5.828$ ,  $df=2$ ,  $p=0.057$ ), however on sub analysis, the Baseline-Final point difference was considered significant after Bonferroni correction ( $z=-2.540$ ,  $df=2$ ,  $p=0.009$ ). There were no differences noted in the npKHA group for credibility ( $\chi^2=1.143$ ,  $df=2$ ,  $p=0.595$ ). Table 21 demonstrates that there was a statistically significant difference noted at baseline ( $z=-2.765$ ,  $df=59$ ,  $p=0.005$ ), Mid-point ( $z=-2.878$ ,  $df=59$ ,  $p=0.004$ ) and Final-point ( $z=-2.941$ ,  $df=59$ ,  $p=0.003$ ) for believability between the two groups, with the pKHA group reporting the intervention more believable than the npKHA group. However, Table 22 demonstrates that credibility of the intervention scores between groups were only significant at the final data collection point ( $z=-2.387$ ,  $df=59$ ,  $p=0.016$ ).

**Table 19 - Comparisons within groups for Believability**

Sample comparison	Time point comparison	Z score	df	Wilcoxon Signed Ranks test (2 tailed Exact)	Statistical test ( $\chi^2$ )	Friedman's Test (2 tailed Exact)
<b>pKHA</b>	Baseline – Mid point	-1.387	2	$p=0.273$	2.800	$p=0.350$
	Baseline – Final point	-1.604		$p=0.183$		
	Midpoint – Final point	-0.333		$p=1.000$		
<b>npKHA</b>	Baseline – Mid point	-0.237	2	$p=0.965$	1.217	$p=0.575$
	Baseline – Final point	-0.943		$p=0.485$		
	Midpoint – Final point	-1.342		$p=0.375$		

**Table 20 - Comparisons within groups for Credibility**

Sample comparison	Time point comparisons	Z score	df	Wilcoxon Signed Ranks test (2 tailed Exact)	Statistical test (X <sup>2</sup> )	Friedman's test (2 tailed Exact)
<b>pKHA</b>	Baseline- Mid point	-1.425	2	p=0.174	5.828	p=0.057
	Baseline- Final point	-2.540		p=0.009*		
	Midpoint- Final point	-1.204		p=0.239		
<b>npKHA</b>	Baseline- Mid point	-0.631	2	p=0.558	1.143	p=0.595
	Baseline- Final point	-0.155		p=0.910		
	Midpoint- Final point	-0.669		p=0.553		

\* Statistically significant post Bonferroni correction (significance level at 0.0167)

**Table 21 - Comparisons between groups for Believability**

Time point	Median		IQR		Z score	df	Mann Whitney U (2 tailed Exact)
	pKHA	npKHA	pKHA	npKHA			
<b>Baseline</b>	2 (probably true KHA)	3 (uncertain)	2-3	2-3	-2.765	59	p=0.005
<b>Mid point</b>	1 (definitely true KHA)	3 (uncertain)	1-3	2-3	-2.878	59	p=0.004
<b>Final point</b>	2 (probably true KHA)	3 (uncertain)	1-2	2-3	-2.941	59	p=0.003

**Table 22 - Comparisons between groups for Credibility**

Time point	Median		IQR		Z score	df	Mann Whitney U (2 tailed Exact)
	pKHA	npKHA	pKHA	npKHA			
<b>Baseline</b>	16	15	13-17	13-16	-0.816	59	p=0.420
<b>Mid point</b>	16	14.5	14-19	13-16	-1.581	59	p=0.115
<b>Final point</b>	16	15	15-19	13-16	-2.387	59	p=0.016

Tables 23 to 25 express the qualitative data on why participants believed they received/did not receive/were uncertain if they received pKHA. These data were analysed in conjunction with reporting of believability as expressed on the Likert type item in Appendix 19. For those who believed that they had received pKHA (Table 23), there was very similar reporting on what influenced that belief, with individuals from both the pKHA and npKHA groups reporting impact upon symptoms, needle sensation and wellbeing as factors in their belief. Interestingly, women in the pKHA group who believed that they had received pKHA, provided more qualitative data than their npKHA counterparts. The largest contrast between the groups was that none of the pKHA group thought they did not have pKHA (Table 24), whereas there were comments made by participants in the npKHA group confirming that they did not believe that they had received pKHA; one comment being around the lack of marks left post treatment and another because they had had no sensations during treatment.

Table 25 demonstrates comments that were made surrounding being uncertain if pKHA had been administered. Both groups put forward statements suggesting no change to symptoms, that they had a relaxation sensation, and unsure of what to expect, as reasons for being unsure, with the npKHA group having an additional category of needle sensation as a factor. Finally, data were taken from dropouts that had occurred and are displayed in Tables 23-25, with nothing in their data giving suggestions or unique information that could have been used to predict drop out.

**Table 23 - Reasons given for believing they had received penetrating KHA**

	Descriptions provided		
<b>pKHA</b>	symptom changes in PPGP (n=28)	needle sensation (n= 15)	wellbeing (n=14)
<b>npKHA</b>	symptom changes in PPGP (n=12)	needle sensation (n=9)	well being (n=6)
<b>Drop outs</b>	needle sensation (n=6)	relaxation sensation (n=5)	it worked (n=1)

**Table 24- Reasons given for believing that they did not receive penetrating KHA**

	Descriptions provided	
<b>pKHA</b>	none recorded	
<b>npKHA</b>	expectations of needling (n=6)	
<b>Drop outs</b>	feel worse (n=1)	expected to feel a needle (n=2)

**Table 25- Reasons given for being unsure if they received penetrating KHA**

	Descriptions provided			
<b>pKHA</b>	no change to symptoms (n=1)	relaxation sensation (n=1)	unsure of what to expect (n=1)	
<b>npKHA</b>	unsure of what to expect (n=9)	needle sensation as a factor (n=8)	no change to symptoms (n=7)	Relaxation sensation (n=3)
<b>Drop outs</b>	needle sensation (n=3)	unsure of what to expect (n=3)	changes to symptoms (n=3)	

#### **7.6.12 Outcome measure completion**

Both NRS for current pain level and NRS for pain over the previous week were completed in full by every woman at every session. The PGQ raised a couple of questions, mainly around whether the items should be completed with PPGP in mind of general pregnancy (despite a clarifying sentence at the top of the outcome measure, added by



the researcher after Chapter 5 results). In addition, several participants asked how to answer PGQ items surrounding ADL that they had not attempted; the participants were asked to fill those in as N/A. Finally, due to the amount of questions in the PGQ, there were five items that continued over onto the back of the page. This was not initially completed by five women, though they did complete on prompting.

### *NRS for pain intensity*

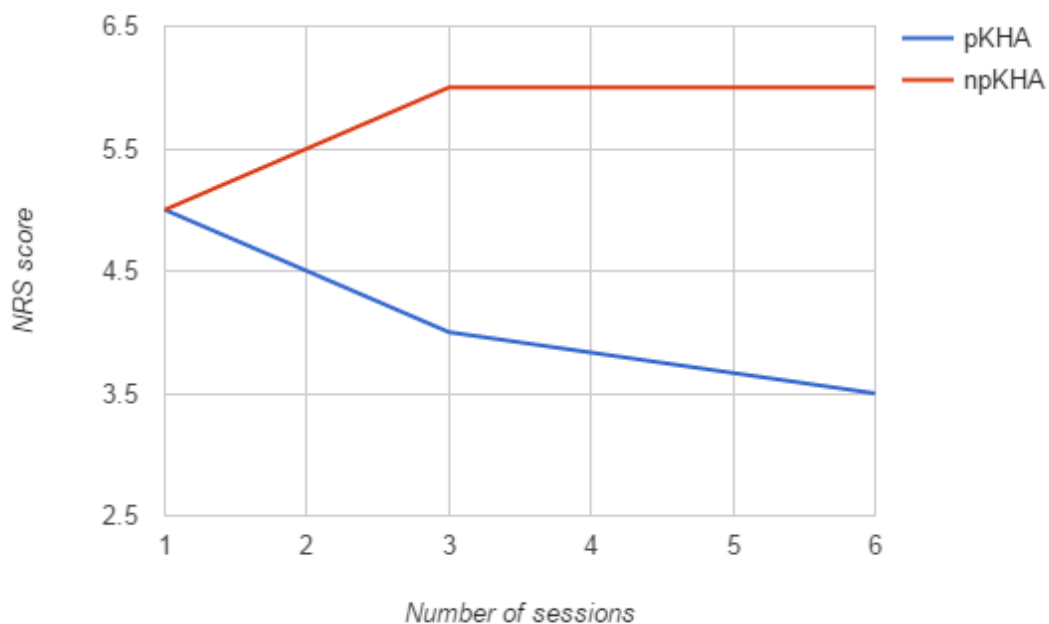
Table 26 displays within group comparisons for NRS for current pain levels, and demonstrates that there was a significant difference between pain scores at Baseline - Final point ( $\chi^2=7.387$ ,  $df=2$ ,  $p=0.023$ ). For the npKHA group, there was no statistically significant difference noted on comparisons between all data points for within group comparisons ( $\chi^2=2.771$ ,  $df=2$ ,  $p=0.256$ ). Table 27 provides further insight into the within group changes, as the trend in median scores reduced from Baseline to Mid-point and from Midpoint-Final point in the pKHA group, but increased in the npKHA group. Table 27 and Figure 2 also display between group comparisons, demonstrating that there was a statistically significant difference at Mid-point ( $z=-2.918$ ,  $df=59$ ,  $p=0.003$ ) and Final-point ( $z=-3.043$ ,  $df=59$ ,  $p=0.002$ ). This demonstrates that the pKHA group decreased in pain intensity over the six sessions when compared to baseline and to npKHA, whereas the npKHA group increased in pain intensity.

**Table 26 - NRS for current pain levels in pKHA and npKHA: Within group comparisons**

Sample comparison	Time point comparisons	Z score	df	Wilcoxon Signed Ranks test (2 tailed Exact)	Statistical test ( $X^2$ )	Friedman's Test (2 tailed Exact)
<b>pKHA</b>	Baseline – Mid point	-1.910	2	p=0.059	7.387	p=0.023
	Baseline – Final point	-2.252		p=0.023		
	Midpoint – Final point	-0.951		p=0.372		
<b>npKHA</b>	Baseline – Mid point	-1.119	2	p=0.280	2.771	p=0.256
	Baseline – Final point	-1.128		p=0.265		
	Midpoint – Final point	-0.143		p=0.894		

**Table 27 - NRS for current pain levels: Between group comparisons**

Time point	Median		IQR		Z score	df	Mann Whitney U (2 tailed Exact)
	pKHA	npKHA	pKHA	npKHA			
<b>Baseline</b>	5	5	3-6	4-7	-0.674	59	p=0.506
<b>Mid point</b>	4	6	2-6	5-7	-2.918	59	p=0.003
<b>Final point</b>	3.5	6	2-6	4-7	-3.043	59	p=0.002



**Figure 2 - NRS for current pain levels**

#### *Sample size calculation*

A sample size calculation for a future definitive RCT was based upon the findings of the primary outcome measure, NRS for current pain. Table 28 demonstrates that in order to have an 80% confidence that type II error would not occur, a total sample of 291 participants would need to be recruited. If the study was to have a 90% power, 376 participants would need to be recruited.

**Table 28 - Sample size calculation**

Threshold of probability of rejecting null hypothesis	Probability of failing to reject the null hypothesis	Z statistic	Relative risk	Sample size required	Sample size adjusted for response rate (32% drop out)
0.05	0.20	1.957	0.425	198	291
0.05	0.10	1.957	0.425	256	376

*NRS for pain over previous week*

For NRS over the previous week, the within group comparisons displayed in Table 29 suggests no statistically significant changes to pain in the pKHA group ( $\chi^2=5.696$ ,  $df=2$ ,  $p=0.056$ ), however on Bonferroni correction for Baseline and Mid-point there was a difference ( $z=-2.858$ ,  $df=2$ ,  $p=0.003$ ). In the npKHA group there were no differences between the groups, and remained so after Bonferroni correction ( $\chi^2=2.082$ ,  $df=2$ ,  $p=0.364$ ). Table 30 and Figure 3 displays comparisons between groups, with the median scores in the pKHA group helping to explain the significant difference between Baseline (median 6) and Mid-point (median 4.5) in the pKHA group observed in Table 29. The only significant difference noted between groups was at the Mid-point ( $z=-2.631$ ,  $df=59$ ,  $p=0.008$ ).

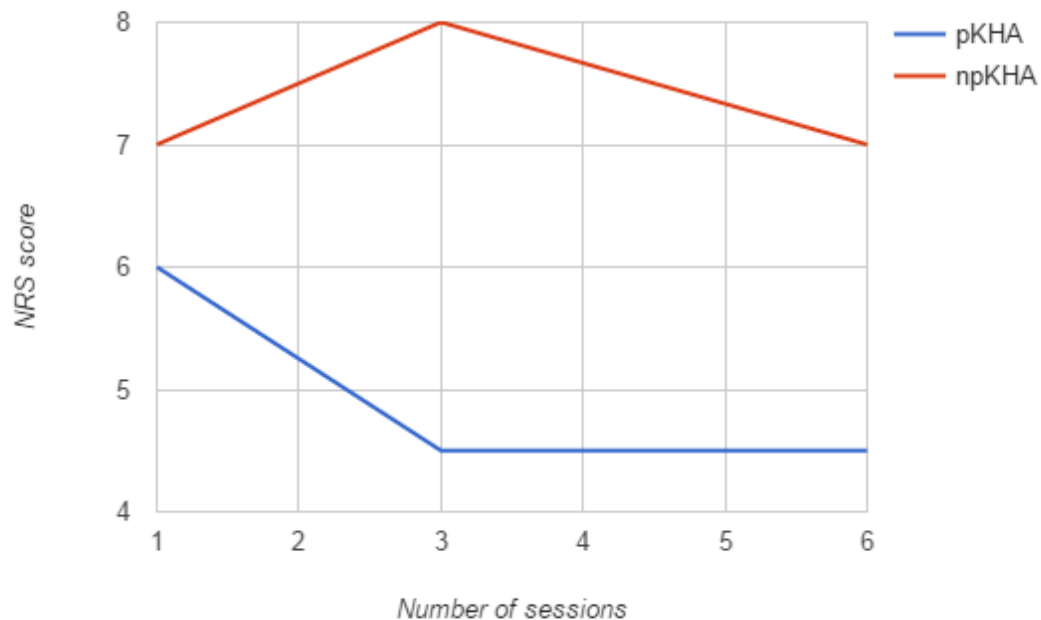
**Table 29- NRS for pain over previous week: within group comparisons**

Sample comparison	Time point comparison	Z score	df	Wilcoxon Signed Ranks test (2 tailed Exact)	Statistical test (X <sup>2</sup> )	Friedman's Test (2 tailed Exact)
<b>pKHA</b>	Baseline – Midpoint	-2.858	2	p=0.003*	5.696	p=0.056
	Baseline – Final point	-1.731		p=0.088		
	Midpoint – Final point	-0.766		p=0.465		
<b>npKHA</b>	Baseline – Midpoint	-0.000	2	p=1	2.082	p=0.364
	Baseline – Final point	-0.696		p=0.503		
	Midpoint – Final point	-1.277		p=0.220		

\* Statistically significant post Bonferroni correction (significance level at 0.0167)

**Table 30 - NRS for pain over previous week: between group comparisons**

Time point	Median		IQR		Z score	df	Mann Whitney U (2 tailed Exact)
	pKHA	npKHA	pKHA	npKHA			
<b>Baseline</b>	6	7	5-7	6-8	-1.312	59	p=0.192
<b>Mid point</b>	4.5	8	3-7	5-8	-2.631	59	p=0.008
<b>Final point</b>	4.5	7	3-7	4-8	-1.608	59	p=0.109



**Figure 3 - NRS for pain over previous week**

#### *PGQ results*

Table 31 displays changes within groups. The pKHA demonstrated no change on Friedman's test ( $\chi^2=5.124$ ,  $df=2$ ,  $p=0.077$ ), though did show a significant difference after Bonferroni correction at Baseline to Mid-point ( $z=-2.664$ ,  $df=2$ ,  $p=0.006$ ). The npKHA demonstrated a significant difference on Friedman's test ( $\chi^2=7.243$ ,  $df=2$ ,  $p=0.026$ ), with the largest difference noted between Baseline and Final-point ( $z=-2.267$ ,  $df=2$ ,  $p=0.021$ ), though this was not significant on Bonferroni correction. Between group comparisons in Table 32 and Figure 4 demonstrates a fluctuating change to PGQ scores for pKHA, and an increase from baseline in PGQ scores for the npKHA group. This demonstrates that function in the pKHA group remained largely unchanged and within the npKHA group it deteriorated. This resulted in statistically significant difference in function at mid-point ( $z=-2.185$ ,  $df=59$ ,  $p=0.028$ ) and Final-point ( $z=-2.046$ ,  $df=59$ ,  $p=0.041$ ).

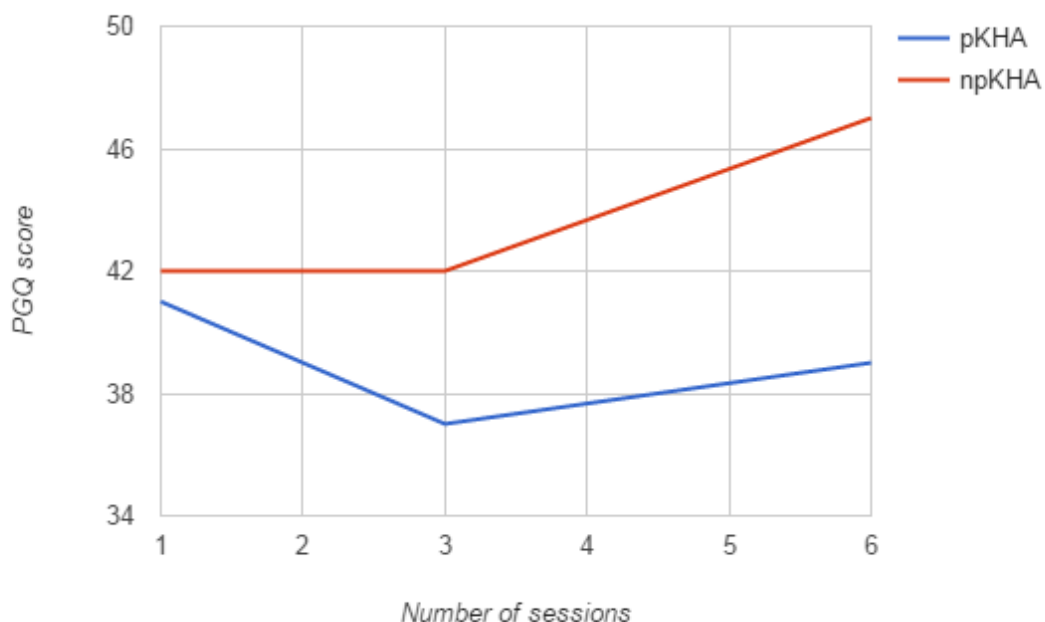
**Table 31- PGQ within group comparisons**

Sample comparison	Time point comparison	Z score	df	Wilcoxon Signed Ranks test (2 tailed Exact)	Statistical test ( $X^2$ )	Friedman's Test (2 tailed Exact)
<b>pKHA</b>	Baseline – Mid point	-2.664	2	p=0.006*	5.124	p=0.077
	Baseline – Final point	-1.157		p=0.256		
	Midpoint – Final point	-1.833		p=0.068		
<b>npKHA</b>	Baseline – Mid point	-0.850	2	p=0.411	7.243	p=0.026
	Baseline – Final point	-2.267		p=0.021		
	Midpoint – Final point	-1.812		p=0.071		

\* Statistically significant post Bonferroni correction (significance level at 0.0167)

**Table 32- PGQ between group comparisons**

Time point	Median		IQR		Z score	df	Mann Whitney U (2 tailed Exact)
	pKHA	npKHA	pKHA	npKHA			
<b>Baseline</b>	41	42	29-52	33-54	-0.610	59	p=0.547
<b>Mid point</b>	37	42	21-48	31-56	-2.185	59	p=0.028
<b>Final point</b>	39	47	26-52	33-57	-2.046	59	p=0.041



**Figure 4 – PGQ scores**

#### **7.6.13 Participants views and experiences (Appendix 13 and 14)**

Although clinical questioning was initially considered as the best method to gather adverse event information, it also provided further information that may be missed by the NRS and PGQ outcome measures, as it provided insight into what women considered valuable to them. Further qualitative information was gathered in the usual clinical questioning manor, surrounding any changes better/worse/same to general health, with the raw data obtained displayed in Appendix 13 and 14. The overall themes of data produced are; 'general effects'; 'effects on symptoms' and; 'other comments'. Appendix 13 captures comments made by participants in the pKHA group throughout the study, which is not measured through the other outcome measures. Under 'effects on symptoms', 11 comments surrounding symptom relief duration were given, three stating they gained



short-term relief, while eight suggested longer term effects.

Symptoms not worsening also appeared to be considered a benefit to participants, indicating the perception that PPGP would normally get worse as pregnancy progressed. Comments such as taking fewer painkillers, and that 'feels acupuncture has made a significant improvement to my life' demonstrate treatment outcomes that were not envisaged in the proposal development of this research. In addition, six participants in the pKHA group indicated that they were able to do more activity since enrolling onto the study such as ADL's and were more active in employed work. However, there were two comments suggesting symptoms had worsened temporarily.

Under 'general effects', there were 11 women who had noted changes to general wellbeing such as sleep improvements and relaxation, both of which were considered valuable. One woman reported her chronic headaches had dissipated since beginning pKHA. For 'other comments', two women reported the baby moving more so, two reported having less movement, all of which did not lead to an adverse event. Finally, Appendix 14 demonstrates data collected from the npKHA group, presented under the same three themes as the pKHA group. There was a huge difference in the amount of information provided, with only five women providing additional information. Under general effects, two women found they slept better after the session and one found sleep had been worse. For 'effects on symptoms', three comments suggested symptoms had improved at least temporarily. There were also two comments that suggested symptoms were getting worse, and one comment that suggested the pain was variable. No 'other comments' were noted.

#### **7.6.14 Results summary**

Forty participants were recruited to the study, in addition to 19 dropouts, over a period of 15 months. Clinicians were willing to refer into the study after the study was made more visible throughout the clinic. Acceptability of the intervention by the PPGP sufferers was excellent, with 18 signaling they would consider receiving pKHA again. However, location of the study hindered recruitment. Further acceptability is observed in that adverse events that were experienced were a reason for attrition in only one case, indicating that adverse events were largely considered by the participants as minor. Baseline demographic data that was collected demonstrates homogeneity, and that credibility and believability remained relatively constant for within group comparison.

However, credibility and believability were noted to be statistically significantly different between groups, with pKHA being recorded as more credible (at the final point) and believable. The outcome measures used were completed correctly without a prompt in the majority of instances, and the results from NRS and PGQ reflect the qualitative comments that participants made, especially around symptom relief by those in the pKHA group. For current pain levels, pKHA within group NRS scores produced statistically significant changes ( $p=0.023$ ), and when compared to npKHA, demonstrated greater reduction at Midpoint ( $p=0.003$ ) and Final point ( $p=0.002$ ). Pain over one week NRS score was only statistically significant at midpoint, with pKHA showing improvement to pain over npKHA, though the median score in the pKHA group had dropped from 6 at baseline to 4.5 at final point. For ADL's, the PGQ was noted to be statistically significant at Midpoint ( $p=0.028$ ) and Final point ( $p=0.041$ ) when pKHA was compared to npKHA, likely due to ADL's becoming more difficult in the npKHA group and only marginally improved in the pKHA group. Marginal improvement, or status quo of symptoms, was considered a benefit from treatment, demonstrated in the qualitative comments made by participants, as

the expectancy was for symptoms to worsen as PPGP progressed. Qualitative comments by 11 women indicate that pKHA had a positive effect on general wellbeing, highlighting the limitations of using only NRS and PGQ to measure treatment outcome.

## **7.7 Discussion**

The aim of this chapter was to develop and implement a study investigating the practicalities of delivering KHA for PPGP. To achieve this aim, the data that were collected followed the recommendations put forward by the NIHR (2015); subsequently, the results displayed here indicate that this aim has been met. This study produces an original contribution to research through being the first KHA study in English for a pregnancy related condition, the first to compare pKHA and npKHA in any English written study, and the first study in the UK to utilise the PGQ as an outcome measure for PPGP.

### **7.7.1 Feasibility and Practicality**

The original three-armed design was quickly identified by the CI as being not feasible to continue with for two main reasons. First, there had been an over estimation of the potential participants available to the study by the physiotherapists in the department.

Three months into the study, only three women had completed six sessions; at that completion rate, only 12 participants would complete the study by the one-year cut off point. This would have reduced any meaningful comparisons on reporting upon impacts of the KHA approaches, as only four participants in each KHA group would be available. Secondly, those that were allocated to the standard physiotherapy group at the four-month point, failed to complete a single outcome measure. This demonstrates that the control arm of the study was not feasible in its current format and not an acceptable approach to warrant continued randomisation. Reasons given by those not wanting to be involved in the study, outlined under 'i Number of eligible patients/willingness of participants to be

randomised', support this. Thus, the two-arm study was subsequently conducted, randomising participants to either pKHA or npKHA, which the researcher here found to be feasible for a number of reasons.

The researcher was able to complete data collection despite being in full time employment, and having to negotiate the intervention delivery around clinic availability. It took 103 days of participant contact to collect the relevant data for 40 completions, and would likely take less days if a full time researcher was employed. This advocates the study as practical to complete in a larger format if funding was appropriated for data collection by a full time researcher.

Results displayed in 'iii willingness of clinicians to identify potential participants' show that initially, physiotherapists were not identifying as many potential participants as originally hypothesised. One of the reasons for the initial slow uptake could be due to the uncertainty around the researcher. Although he was known as an acupuncture tutor and qualified physiotherapist, his experience with women's health and pregnancy related conditions was relatively unknown to the physiotherapy team. This could have led to individuals being unsure as to who they should refer into the study, though this was not communicated through the post study discussion in 'viii Physiotherapy staff views on study'. The recruitment rate did improve after discussion with the physiotherapy team, and perhaps an indicator that the physiotherapists considered the study to be of some benefit was the uptake of acupuncture into their standard practice as the research developed.

At the beginning of the study, none of the team used acupuncture, but by the time the study had completed, all of the physiotherapists had attended an acupuncture course

and used acupuncture in their daily practice. This consideration of the referrer's views highlights the importance of ensuring that recruiting staff are not only engaged with the research aims, but also have trust in the researcher prior to commencing the study. This is an important consideration for feasibility studies aiming to inform a definitive RCT, as recruiters need to be engaged with the research in order to identify potential eligible participants.

### **7.7.2 Acceptability and Credibility**

Acceptability of the study can be observed in the completion rates for the pKHA group, as only four drop outs from 24 recruited, occurred (see figure 1). When compared to the study centres' usual DNA rate of 50%, this suggests that pKHA provided a service that was considered helpful, and that attending six sessions was not a barrier, as long as symptoms were improving. The pKHA group in particular were very supportive of the study, with most participants stating in 'vi Acceptability of pKHA and npKHA' that they continued to attend because of the benefits they attained, and 18 of those in the pKHA group would seek out pKHA again. Acceptability of the study was likely to have been enhanced because adverse events that occurred were transient. There were no serious side effects reported and only one participant withdrew from the study as a result of an adverse event (see Appendix 22).

Finally, credibility of pKHA is likely to have led to it being an acceptable approach, as it was rated consistently as 16/20, indicating on average, participants mostly agreed that the treatment seemed credible (see Appendix 20 for credibility scale). Therefore, the two-armed study is considered feasible, acceptable and practical to be extended to a large-scale study, with the recruitment rates supporting further investigation into KHA for PPGP. This meets the aims of a feasibility study as outlined by Arian *et al.* (2010), and

by establishing its acceptability, would allow for further evaluation of a complex intervention via a definitive RCT, as put forward by Craig *et al.* (2008).

### **7.7.3 Recruitment and attrition**

The NIHR (2015) guidelines for feasibility studies, which in turn supports the MRC framework for complex interventions, stipulate that recruitment and attrition rates be investigated prior to a large-scale study. Forty completions and 19 dropouts within a 15 month period were attained. Taking into account that the CI worked part time on data collection, it could be argued that pro rata, completion rates in a larger study should consider 40 participants per 8 months, if the researcher worked full time. In comparison to the current literature, this completion rate would seem to be appropriate. Although Erkdahl and Petersson (2010) aimed to recruit more than 40, they were only able to recruit a total of 36 women over a 15-month period. However, Wang *et al.* (2009) achieved 159 completions within 35 months, and Elden *et al.* (2005) managed to recruit 321 women over a two-year period. However, Wang *et al.* (2009) participants were only enrolled for two weeks, meaning there was less time for attrition, and Elden *et al.* (2005) data collected from 27 different midwifery centres. Based upon the context of Wang *et al.* (2009) and Elden *et al.* (2005), the completion rate in Erkdahl and Petersson (2010), and the part time recruitment adopted for this study, this chapter has shown that recruitment to a larger study would be realistic.

When considering the amount of dropouts for the total study, 19, it is large compared to Elden *et al.* (2005) (they had 38 drop outs in 2 years out of 321 recruited). However, there was only a 16.6% drop out amount in the pKHA group, compared to 14.4% in the acupuncture group in Elden *et al.* (2005). The NIHR (2015) recommend that evaluation of feasibility should take into account the context in which the intervention is delivered.

The DNA rate within the department of where this study was conducted was 50%; therefore, within this demographic, a 16.6% drop out rate for the pKHA group, and even an overall study drop out of 32%, is still considerably lower than would be expected from the antenatal population this study was drawing upon.

Several reasons for non-completion were put forward in 'ii Study attrition/the practicality of delivering the intervention in the proposed setting' by those who dropped out, though not all participants responded to requests for leaving the study. It is possible that some individuals did not complete in the npKHA because of unblinding. One woman stated she discontinued attendance to the study because she had chosen to look under the blindfold whilst the npKHA intervention was administered. This information was gained through the post study discussion with the physiotherapists and not directly to the researcher, indicating that individuals may not always be willing to give the true reason for non-completion to the CI directly. Perhaps the most plausible reason for such a high DNA rate in the npKHA group is simply because they were not getting any benefit from the treatment, which is consistent with the findings of Smith and Crowther (2002). This is supported by NRC (2010), who stated one of the most common reasons for drop outs is ineffective treatment, and is consistent with findings displayed in Chapter 6, whereby some interviewees stated they would only consider attending for a treatment on a regular basis if they had complete resolution, or dramatic changes, to their symptoms (page 159).

Furthermore, additional qualitative comments in Appendix 13 and 14 demonstrate that the npKHA group rarely suggested any general wellbeing benefits when compared to pKHA, perhaps indicating an important role these effects have on continuing with treat-

ment. Finally, 17 of the 40 who did complete, from both pKHA and npKHA groups, commented in the end of study questionnaire that the reason they continued being involved in the study was because they were getting symptom benefits. This suggests that they would not have continued if they did not gain any benefits.

Another factor that may have influenced recruitment and retention is the gender of the CI, as discussed in Chapter 3. Bishop *et al.* (2011) discussed the potential factors that may relate to why people choose a particular health care practitioner, with same sex preferences emphasised in the literature (Bishop *et al.* 2011). Their results indicated that some women would only attend a consultation with a male acupuncturist if they could bring along a chaperone, i.e. their husband (Bishop *et al.* 2011). They also found that people went to those acupuncturists whom had qualifications in the area and whom had personality about them. Bishop *et al.* (2011) did find that the preference was to have female acupuncturists and those who had a medical qualification, and so as the CI in the study outlined in this chapter was male, gender could have potentially dissuaded some women to enrol onto the study. Additional retention issues were highlighted in the location of the research and commitment needed to complete the study. For some, the location being in a city centre hospital proved to be too prohibitive, whilst others commented that attending for six sessions was too much of a commitment (see ii Study attrition/the practicality of delivering the intervention in the proposed setting); again, the interviews in Chapter 6 did suggest that this may be the case. Although these were unavoidable for this study, there are suggestions made later in this chapter on how to minimise the location impact.

#### **7.7.4 Trends in intervention outcome**

The randomisation process into the two-armed study appeared to be appropriate, as



both demographic data and initial outcome measure scores in NRS and PGQ were homogenous at baseline. This means that if this randomisation process was continued to be observed in any future larger study, any differences observed between the two KHA groups could be more confidently stated as emanating from the independent variable (skin penetration). Furthermore, those included in this study reflect the national maternal age average of 30, discussed in Chapter 2 (page 32) (ONS, 2015), suggesting those recruited are likely to be representative of the general pregnant population. For the women in this study, the gestation in which PPGP began, second trimester, is consistent with those women who participated in the Chapter 6 study. However, enrolment onto the study was not until the third trimester, which supports the views of physiotherapists that PPGP progresses from an initial severity that does not warrant intervention, to becoming more troublesome as the pregnancy continues. It would also support work by Kanakaris, Roberts, and Giannoudis (2011) who put forward that PPGP requires intervention in the third trimester. All other demographic factors were considered equal across the groups, and so would not be considered as a cause of any differences in NRS or PGQ scores at mid and final points.

#### **7.7.5 Suitability of the outcome measures: Pain**

As outlined by Arain *et al.* (2010), the main focus of any feasibility study should not be on effectiveness, although reporting trends in data helps to advocate for a definitive RCT. The NRS for pain at present demonstrated a trend of decreasing pain in the pKHA group at both midpoint and final point (Table 26 and Figure 2), whilst the npKHA group recorded a slight worsening of symptoms compared to baseline (Table 26 and Figure 2). Although taking measurements on pain at present considers only a snapshot of their pain experience, the average difference between the groups was statistically significant at midpoint ( $p=0.003$ ) and final point ( $p=0.002$ ) (Table 27), suggesting this decrease in

pain was noted regularly in the pKHA group. These findings are comparable to Wedenberg, Moen and Norling (2000), Kvorning (2001), Da Silva *et al.* (2004), Wang *et al.* (2009) and Elden *et al.* (2005), whilst being different findings to Elden *et al.* (2008) who found no difference to pain scores.

However, the NRS for pain over the last week provides a different take on KHA impact upon pain, as the only statistically significant difference between the two groups was noted at midpoint ( $p=0.008$ ) (Table 29). However, the trend in the pKHA group (Table 29 and Figure 3) indicates a declining of NRS scores, demonstrating the importance of displaying data findings in conjunction with p values. The difference between NRS at present and NRS for pain over previous week could be due to an unspecified variable within the treatment session which reduced pain at present, or it could be due to recall bias for the scores in the NRS over last week group, though the qualitative data supporting these scales provide a richer insight into the importance of the pain relief recorded.

Additional qualitative data provided insight into the effects of KHA, as although one off comments cannot be used to measure effectiveness, they can help to support outcome measures or uncover benefits that were not originally hypothesised. Appendix 13 suggests that pKHA benefited symptoms in the majority of women, noted frequently by participants, although the duration of symptom relief varied. The relevance of this additional qualitative data is apparent when considering the limitations of the NRS outcome measure, as improvements to symptoms of pain lasting for one day would unlikely be detected by these scales, yet were considered worthwhile benefits to some PPGP sufferers. In addition, participants considered no progression of pain to be a positive sign, as they expected their symptoms to worsen as the pregnancy progressed. This would therefore indicate the NRS for pain over the previous week scores displayed in Table 29 to be an

important change in symptoms to PPGP sufferers, despite being statistically non-significant.

Further insight into KHA benefits were observed, with the majority of participants in the pKHA group stating that they had improvements in relaxation and sleeping (Appendix 13). This insight into additional KHA benefits would not have been observed without adopting a mixed methods approach, advocating this methodology and combination of NRS and patients views and experiences as the most appropriate for this research topic. However, impacts of KHA upon ADL's is less clear for a number of reasons.

#### **7.7.6 Suitability of the outcome measures: Function and ADL**

The PGQ findings produced statistically significant results in favour of the pKHA group at midpoint ( $p=0.028$ ) and final point ( $p=0.041$ ) (Table 30 and 31). This suggests that pKHA has more benefit than npKHA upon ADL's, yet the median scores provided in Table 31 provides greater insight. It could be argued that the impact of two to four points may have little bearing on the PPGP sufferer, and so could be considered inconsequential. However, taking into consideration the belief that PPGP will progressively worsen (as discussed in Chapter 6 by the interviewees), these small changes could still be considered worthwhile. In addition, there are several reasons for the observed PGQ scores, which may mean that these results do not accurately portray the actual effect.

First, despite it being advocated by Stuge *et al.* (2011), Grotle *et al.* (2012), and Wild (2014) because of its good levels of validity and reliability, Grotle *et al.* (2012) acknowledge that the PGQ has not been tested for responsiveness to change. It is possible that the PGQ is not sensitive enough to record changes to ADL's that are considered significant to the PPGP sufferer, especially when the data are amalgamated for

data analysis. An observation from the researcher here is that if a participant was to report only one or two ADL's to have changed, yet recorded other ADL's to have remained similar or worsened, it could give little impact upon the overall score. Looking at the PGQ results in Table 30 and 31, it would seem that there is not much change to ADL. However, participants put a lot of emphasis on individual ADL as opposed to generic ADL's in the additional qualitative comments displayed in Appendix 13, and without this supporting qualitative data, this contextual factor would have been lost. Finally, the interpretation of the PGQ may have influenced the results recorded.

Often, women in the pKHA group reported being able to do more, compared to when they first enrolled onto the study. As the PGQ asks the difficulty of completing a task, it is debatable as to whether the participant may now be doing the tasks more often, or it taking longer for difficulty to be observed, yet still be considered difficult if comparing to what they could do pre PPGP. This factor could be dealt with in a subsequent larger study if completion of the PGQ was accompanied by a thorough description of how to complete it. The PGQ would therefore appear to be a suitable outcome measure for any future definitive RCT.

#### **7.7.7 Potential pain mechanisms involved**

From this study, it is unclear exactly which element of the KHA ritual brought about improvements to symptoms, though several suggestions can be made. First, it could be due to the study design. The amount of participants within this study do not match that of larger scale work by Elden *et al.* (2008), and so with more women recruited to the study, allowing for more accurate generalisation to the population, it may be found there is no improvement to symptoms. Therefore, further investigation with an adequately powered study is required before making claims into KHA effectiveness on PPGP. When this

study is conducted, as discussed above, an appreciation must be given to the outcome measures themselves, as they may not be robust enough to accurately report, or potentially overstate, changes to symptoms. This does, however, apply for both sides of the argument, as treatment effect could be larger. However, the qualitative comments from individuals suggest that, if anything, the outcome measures used failed to express the amount of benefits provided by KHA. It would therefore be appropriate to take NRS and PGQ measurements, and in addition to qualitative comments, include an outcome measure such as the EQ-5D to measure wellbeing effects.

Next, improvements could be as a result of natural progression of the condition. Without a group that receives no treatment, it is impossible to be confident beyond doubt that improvements would not have happened if they had received no intervention. However, clues do present themselves in studies that have had control groups with little intervention, such as Da Silva *et al.* (2004), which suggests the natural progression is worsening of symptoms until they give birth. Some of the qualitative comments made by participants confirm clinician reports of PPGP tending to fluctuate in severity, and qualitative comments made in Chapter 6, suggest that PPGP does progressively get worse. This is supported by scores observed in the NRS for current pain in Table 27 and PGQ in Table 31, as symptoms do tend to worsen when randomised to the npKHA group.

Credibility of an intervention is considered a potential influencing factor upon symptom recording (Vincent and Lewith, 1995). In previous acupuncture studies such as Sherman *et al.* (2002), Elden *et al.* (2005) and Smith and Crowther (2002), credibility has been considered a variable that may impact upon results, and thus should be measured to gauge whether it is potentially attributable to any differences between groups. Credibility assessment in this feasibility study was considered non-significant at baseline ( $p=0.414$ ,

Table 20), suggesting that the groups were homogenous at this point. If credibility had remained consistently similar across the two groups throughout the data collection, then it could be considered that it had been controlled for, and thus not an impacting factor on differences in NRS or PGQ scores. Although at midpoint there was no difference in credibility between groups, at the final point there was ( $p=0.017$ ); thus, credibility could have influenced NRS and PGQ scores acquired at the final point. It could be that there was an element of unblinding, yet as this was not reported upon in Table 23-25, it is unclear. As with the attrition rate discussion earlier, a more plausible reason for an increase in difference in credibility could be due to more positive effects on symptoms in the pKHA group. The medians provide further description of what was observed, with a score of 16 in the pKHA group and 15 in the npKHA group indicating that this difference was not considerable. It also suggests that looking at the npKHA group in isolation, the intervention seems to be deemed credible by PPGP sufferers.

Although the researcher here would advocate credibility assessment in any future study, these results suggest that npKHA is a valid approach to use when investigating the impact that skin penetration in the hand has on symptoms of PPGP. This provides an original contribution to knowledge, as this is the first study that has assessed the credibility of a non-penetrating approach to acupuncture that is delivered solely to the dorsum of the hand. This is in agreement with findings by Sherman *et al.* (2002), who also found their non-penetrating approach to be credible. However, although credibility is considered an important factor in comparative studies of acupuncture, an interesting trend is noted within the believability scores.

All between group comparisons displayed in Table 21 for believability are statistically significantly different. The npKHA group consistently reported being uncertain, whereas the

pKHA group fluctuated between probably and definitely true KHA. Taking these results in isolation, it is not surprising that the pKHA group considered the intervention to be penetrating. However, the results suggest that the npKHA approach produces an effect that means the recipient cannot say whether they have received a true intervention or not, meaning there has been very little unblinding. These findings, when tied together with the credibility findings, support the npKHA approach, developed in Chapter 5 and outlined in the methods section in this chapter, as an appropriate non-penetrating approach to be adopted in future larger scale studies. Although, as with the NRS and PGQ, internal validity of the outcome measures may be the reason for the results gained.

The difference found between the Likert type item for believability and credibility assessment could be due to error inherent within the outcome measures. Carifio and Perla (2007) highlight the issues around reliability of a single item Likert type, and advise that this should not be conducted where possible. As outlined in Chapter 5, the believability outcome measure was adopted in the absence of any other measure, and that it was comparable to a scale utilised by Sherman *et al.* (2002) in their penetrating versus non-penetrating study. In addition, although the credibility scale, which is a Likert scale, has been adopted by numerous researchers such as Elden *et al.* (2008), the scale itself does not appear to have been subjected to rigorous reliability and validity testing for acupuncture studies. This said, it remains the standard approach to assessing credibility within acupuncture studies, as so for the purposes of this study, the results emanating from this scale should take priority over the believability outcome measure.

In addition, the ritual of KHA could be the most important factor in improvement of symptoms, with the act of penetrating the skin a contributor (albeit statistically significant in NRS and PGQ). Chapter 3 highlights the neurophysiological changes that are specific to

needle insertion, observed in studies such as Chae *et al.* (2009) and Harris *et al.* (2009). These papers could explain why pain relief was found in the pKHA group, and perhaps why there was a difference between the groups. Therapist-participant interaction, credibility, and treatment expectancy, would all have had some impact upon symptoms. Taking this further, the qualitative data suggests that improvements to symptoms in themselves may have strengthened credibility, which in turn could have a larger impact upon symptom improvement. The ritual of KHA could also explain why some randomised to the npKHA group also experienced benefit, highlighting the need to maintain all parts of a treatment, rather than focus purely upon one element of a treatment, to provide an ethically sound intervention for PPGP sufferers. It could have been produced by cognitive modulation through discussion surrounding the potential benefits of attending the study, such as pain relief and improvement to ADL's. Kong *et al.* (2006) found expectation to impact upon symptom reporting, therefore it is feasible to suggest it as a potential factor. Of course, an uncontrolled for, unknown variable could be the cause of improvements, just as much as the treatment effect could be as a result of a sum of all parts.

#### **7.7.8 Study strengths**

The study design is considered to be acceptable, feasible and practical to conduct on a larger scale, as recruitment and retention rates, alongside positive qualitative comments, indicate participants felt that the study was worthwhile. As both the NIHR (2015) and the MRC framework (Craig *et al.* 2008) indicate that these are important factors to measure prior to evaluation of a complex intervention, the fact that this study has met its aims means the method is worth extending to a large scale, fully powered study. A further strength is that this study is comparable to previously published research into acupuncture for PPGP, adopting outcome measures that measure pain and function. The use of the PGQ could be considered a strength over all other published work, as it is the only



validated outcome measure for PPGP. In addition, the measurement of credibility, believability and demographics has attempted to disclose variables that may or may not have influenced outcomes observed in the NRS and PGQ. The use of a mixed methods approach is also considered a strength, as authors such Vernhoef *et al.* (2005) and Bishop and Holmes (2013) (discussed on pages 96-97) advocate this method for acupuncture studies. By utilising qualitative data alongside the outcome measures, findings were contextualized and therefore better understood.

#### **7.7.9 Study limitations**

The results presented here should be compared to existing literature cautiously, not least because of the lack of a fully powered sample. To reduce researcher bias, the researcher should not be involved with data collection, analysis and synthesis, as there may have been an unconscious impact upon how the data was collected. Although the raw data were verified and scrutinised by the CI's supervision team, who were not involved in the data collection, thus the results inputted and presented here are verified, it may have been unconscious body or verbal language used in the treatment sessions which influenced the participants to record what they did. As outlined in Chapter 3, Kaptchuk *et al.* (2008) found that the way a clinician delivers information to a patient can influence outcome; therefore the researcher here may have had a more empathetic approach with the penetrating group and a less empathetic approach with the non-penetrating group. However, as the researcher was acutely aware of this being a potential variable, he attempted to keep interactions with the participants very similar. Also, as put forward in the method section of Chapter 5, controlling for therapist-participant interaction by using the same researcher for all interactions can be considered a strength.

A further weakness in the data analysis can be observed in the method of dealing with drop out data. The researcher here decided upon a method adopted by Elden *et al.* (2008) of intention to treat analysis, whereby the previously inputted data point was carried forward if some data was missing. This ensures that all participant data is included, yet the main weakness is that when dealing with conditions such as PPGP, which are likely to progressively get worse, using previously recorded data could not accurately represent the usual course of the problem. Put into context for this study, because there were more drop outs in the npKHA group, stronger differences between groups may have been observed if only data that had been collected for all those that completed the study were included. Although this approach has been adopted by a multitude of researchers, Dziura *et al.* (2013) advocate a more robust method of multiple imputation, which can be used in fully powered studies.

It could also be argued that additional outcome measures should have been utilised to measure impact on the general wellbeing and sleep impacts. This would be supported by the findings in Chapter 6, as well as the study by Bjelland *et al.* (2013) and be comparable to Elden *et al.* (2008). Additionally, the use of the PGQ, although shown to be valid and reliable by Stuge *et al.* (2011) and Grotle *et al.* (2012), is still in its infancy, and so may prove to be not appropriate to use for measuring changes to symptoms for ADL's. It could, therefore, be argued that despite it being the only PPGP specific outcome measure, another outcome measure with a stronger validity and reliability claim, such as the DRI, would have been more appropriate. Outcome measure validity and reliability issues are extended to the credibility and believability scales that were used, meaning that the researcher can be less sure that the results obtained were as a result of KHA.

As discussed in Chapter 4, qualitative researchers often point to mixed methods research as producing only superficial qualitative data and data analysis. However, the purpose of the qualitative data in this phase was shown to be valuable in not only assessing acceptability of the study, but also providing a deeper understanding of symptom changes whilst providing insight into general pregnancy symptoms that KHA may be beneficial for.

#### **7.7.10 Future research**

Prior to implementing a complex intervention, the MRC recommend that thorough feasibility testing is conducted (Craig *et al.* 2008). On the basis of the findings put forward within this chapter, it would be feasible and acceptable to conduct this study as a fully powered two arm comparative study, with its main aim to investigate effectiveness of pKHA vs. npKHA for PPGP. A mixed methods design has been shown to help capture a range of data that pure quantitative or qualitative approaches could not attain, providing insight into study acceptability whilst also demonstrating trends in symptom outcomes. The cost implications, from a study materials perspective, would not be prohibitive, and the willingness of both clinicians and potential participants to be involved with the study should mean recruitment would not be an issue. The researcher here would advocate a strong emphasis on the study aims within the physiotherapy department from the beginning to maximise recruitment potential, with the techniques adopted in 'iii Willingness of clinicians to recruit participants' advocated. However, there are several alterations that the findings of this study would support in making.

When looking to progress this study into a larger scale project, the researcher here would suggest a data collector physiotherapist who provided the interventions, and a

separate data analyser, to reduce researcher bias. For example, the additional qualitative data collection could have been influenced by the researcher, by not asking as many questions surrounding additional comments with the npKHA group. Although the researcher was conscious to keep the interaction similar across the groups, the reader of any published research findings would more likely have confidence in this type of data being collected by an individual separated from the data analysis. Having a dedicated researcher to administer the intervention would attract additional costs, but it may also improve recruitment and retention rates to the study if they were at the clinic on a full time basis. It may also mean that the full time researcher could investigate other potential avenues for recruitment, such as through community midwives who see almost every pregnant woman in England. Taking into account findings by Bishop *et al.* (2011), if the person providing the intervention were female, it may lead to an increase in enrolment to the study. There could also be potential scope to conduct the study in more community-based settings rather than in a city centre hospital, removing one of the barriers to recruitment and retention.

Table 28 displays the numbers needed for a fully powered study. Given the recruitment rate of this feasibility study (59 participants per 8 months), it would require up to 40 months to attain 291 participants and up to 56 months to achieve 376 participants. Therefore any funding application would need to consider funding to cover the duration of the project.

Another consideration would be the outcome measures adopted. The outcome measures of NRS, PGQ, credibility and believability would remain, though would be supplemented with additional outcomes pertaining to general wellbeing, such as the EQ-5D. In addition, a DRI could be included to be used alongside the PGQ providing a level of

validity and reliability testing for the PPGP specific outcome measure. However, it can be considered a flaw in research design to implement too many outcome measures, so it would only be appropriate if deemed necessary by an ethics panel. Slight administrative changes to the PGQ could also be made to ensure the outcome measure was completed in full without the need for prompts from the researcher; a simple 'PLEASE TURN OVER' on the front page may help.

Finally, continued reporting of attrition in the study population should be made. The dropout rates, in particular for the npKHA group, are high when compared to other acupuncture studies within PPGP (Elden *et al.* 2005; Elden *et al.* 2008; Wang *et al.* 2009); however when compared to the usual DNA rate of the physiotherapy department, it is lower than expected. If this study was to be conducted over several sites, the usual DNA rate should be recorded in order to contextualise the dropout rates recorded. Any missing data, whether it be from dropouts or from incomplete outcome measures, could be addressed using Multiple Imputations, an approach favoured by several statisticians (Dziura *et al.* 2013).

#### **7.7.11 Chapter summary**

Previous investigations into acupuncture effect upon PPGP have produced favourable outcomes, with research such as Elden *et al.* (2005), Elden *et al.* (2008) and Wang *et al.* (2009) all indicating acupuncture to be beneficial to symptoms of pain and function. The best acupuncture approach has yet to be demonstrated, with Elden *et al.* (2005), Elden *et al.* (2008), Wedenberg, Moen and Norling (2000), Kvorning *et al.* (2004) and Da Silva *et al.* (2004) all using body acupuncture approaches, and Wang *et al.* (2009) adopting a microsystems approach. The study here aimed to develop and implement a study inves-

tigating the practicalities of delivering KHA for PPGP, and achieved this through completion of the study within 15 months. Participants and referring physiotherapists both reported the study as acceptable, indicating that a larger fully powered study would be feasible. In addition, promising trends in pain reduction and ADL, alongside qualitative comments around benefits to general wellbeing, indicate that KHA may be an effective approach to dealing with PPGP. This study produces an original contribution to research through being the first KHA study in English for a pregnancy related condition, the first to compare pKHA and npKHA in any English written study, and the first study in the UK to utilise the PGQ as an outcome measure for PPGP.

## Chapter 8

### General Discussion and Conclusions

#### 8.1 Key findings and original contribution

This thesis aimed to produce original research in a number of areas, and has been guided by the MRC framework for complex interventions (Craig *et al.* 2008). Core to the evaluation of any intervention is thorough feasibility testing, which this mixed methods approach has achieved. The first aim of the thesis, to develop a believable npKHA approach, and the second aim, to measure KHA acceptability, were initially attained through the study in Chapter 5. This was the first study of its kind to investigate a non-penetrating form of acupuncture based solely on the dorsum of the hand, utilising an outcome measure that draws upon quantitative and qualitative data. This was an important step to undertake before conducting the feasibility study in Chapter 7. Although the method of non-penetrating acupuncture was an adaption of Sherman *et al.* (2002), this thesis provides original knowledge into the perception of needle penetration, in so much as that the hand can be a viable area for investigation using non-penetrating acupuncture.

In addition, the mixed method approach of including a Likert type item and qualitative questions helped to demonstrate the factors which lead people to believe they have received a penetrating needle. This helped with the method of delivery in Chapter 7, and subsequent analysis of believability and credibility of the npKHA approach in the feasibility study in Chapter 7 demonstrated it to be an appropriate non-penetrating acupuncture intervention. Therefore, the combined findings from Chapter 5 and 7 will help to inform future research looking to adopt a non-penetrating approach to acupuncture, by ensuring the adoption of techniques such as rustling needle packaging. This can help to prevent

unblinding in subsequent studies, and can be used in the proposed definitive RCT investigating the effectiveness of KHA for PPGP.

The third aim of this thesis, to gain an understanding of PPGP as experienced by women in the UK, was attained through eight qualitative interviews discussed in Chapter 6. This study ultimately produced findings that will add to the current understanding of PPGP, and has helped to inform a revised definition of PPGP to consider it as a biopsychosocial entity. The researcher here puts forward this potentially new definition later in this chapter under '8.4 Further recommendations for future research'. Factors such as lack of information highlight that PPGP is not expected by pregnant women, despite its high prevalence rate. These findings were in line with almost every existing qualitative study, and thus needs to be acted upon. The RCOG (2015) have issued some information for the general public on what PPGP is, however this is not likely to be the best method in which to disseminate information to the pregnant population. Due to the amount of literature a pregnant woman already receives on their initial midwife appointment, it would seem most appropriate to include PPGP as part of this. By doing so, the pregnant women may feel less anxious when symptoms of pain arise around the pelvis, and could expedite referral to a physiotherapist. This could prove to be a valuable intervention, as findings not only from Chapter 6, but authors such as Wellock and Crichton (2007), suggest the physiotherapist provided support which made managing PPGP easier to cope with.

Further findings from Chapter 6 include an explicit link made by the interviewee's between the pain suffered as a result of PPGP and emotional discomfort. Although this has been speculated by previous qualitative authors such as Persson *et al.* (2013), the study in Chapter 6 is the first to display the PPGP sufferer's views on the connection. Further original insight into PPGP was observed through the expectation of PPGP, as although



participants expected symptoms to worsen as the pregnancy progressed, there appeared to be a lack of knowledge surrounding the potential to develop ppPPGP. This would obviously be aided by the aforementioned improvement to information provision.

Qualitative research in the area of PPGP is growing, providing a rich insight into how PPGP impacts upon the sufferer. The study conducted in Chapter 6 reveals that sufferers based in the UK are in many ways comparable to their European counterparts, lending weight to adopting established interventions and applying them to the UK population. To the author's knowledge, this study adds several original contributions to knowledge through being the first UK based exploration of PPGP sufferers views, providing discussion around interviewee's expectations of treatment, being the first to adopt a pragmatic philosophy in exploration of PPGP views, expressing views of PPGP sufferers upon the PGQ, and being the first exploration of views upon PPGP by a male lead author. This combination of uniqueness provides a different dimension to previous published work, and helps to support current literature whilst providing fresh insights into PPGP.

However, despite concerns surrounding the stature of qualitative data within mixed method studies, Chapter 6 demonstrates that it can be used effectively to help provide answers to broad questions surrounding issues that are not well understood or defined. This should stimulate further research using qualitative methods to gain a deeper understanding of PPGP within the UK, whilst advocating the use of mixed methods research for complex health conditions. Finally, the findings from Chapter 6 aided the study in Chapter 7, through confirmation of the PGQ as an appropriate outcome measure (as considered by eight PPGP sufferers). It also gave insight into what PPGP sufferers would consider an acceptable treatment approach (i.e. frequency of hospital attendance), and ensured that the women enrolled had appropriate access to information on

PPGP and women's health physiotherapists, as these were considered important to the interviewee's in Chapter 6. This means that any future definitive RCT to be conducted has been partially informed by stakeholder views, something which the MRC framework recommend (Craig *et al.* 2008).

The final aim of the thesis, to develop and implement a study investigating the practicalities of delivering KHA for PPGP, was achieved in Chapter 7. This is an important part of feasibility testing, which the MRC framework put forward as integral to the development of a complex intervention (Craig *et al.* 2008). It built upon knowledge gained from both Chapter 5 and 6, influencing the method of delivery and the researcher's understanding of PPGP. Despite 19 dropouts from a total recruited sample of 59, the study was deemed feasible, as both clinicians and participants considered it to be acceptable, as evidenced by the end of study questionnaire discussed in Chapter 7. In addition, trends within the data collected through NRS and PGQ would suggest that pKHA might positively impact upon symptoms of PPGP. Furthermore, Chapter 7 utilised a feasibility design within a mixed methods framework, allowing the researcher to explore the wider impact KHA had upon PPGP sufferers. This produced data on unexpected benefits to general wellbeing, relaxation and sleep that would have been missed if qualitative data had not been collected. This suggests the introduction of acupuncture may have additional benefits to other areas of pregnancy.

As outlined in Chapter 3, Downs and Hausenblas (2004) found that a barrier to exercise was physical limitation; if KHA improved physical limitations, something which the PGQ results within Chapter 7 would suggest, it may improve activity levels, which can help protect against gestational diabetes (Sanabria-Martínez *et al.* 2015). However this would warrant further in depth study. Rost *et al.* (2006), discussed in Chapter 2, found that

those who receive treatment for PPGP during pregnancy were less likely to develop ppPPGP. Therefore, it could be that KHA has a preventative impact upon ppPPGP, though this would require a longer follow up to measure any impact. Additional outcome measures looking at sleep and general wellbeing, would likely add further understanding of KHA impact on PPGP, and should be investigated further in any future large-scale study. The discussion in Chapter 7 surrounding the outcome measures adopted serves to highlight how utilising a test that is not rigorous and reliable can impact upon outcome.

The use of the PGQ within Chapter 7 provides originality to this thesis, as it is the first randomised study involving KHA to use it as an outcome measure. Further validity and reliability testing is needed for the PGQ, credibility and believability outcome measures as outlined in the discussion section of Chapter 7. These scales may have inherent limitations to them, which could impact on issues such as sensitivity to change and thus not provide the most accurate portrayal of symptoms. However, the PGQ is the only available ADL outcome measure considered to be PPGP specific, which should, therefore, warrant its inclusion into PPGP investigative studies. In addition, the PGQ was considered an appropriate measure by the participants in Chapter 6 and 7, thus lending a level of validity to the outcome measure, which is supported by Stuge *et al.* (2011) and Grotle *et al.* (2012).

This study produces an original contribution to research through being the first KHA study in English for a pregnancy related condition, the first to compare pKHA and npKHA in any English written study, and the first study in the UK to utilise the PGQ as an outcome measure for PPGP. Finally, throughout all three phases of this research, it has been considered an acceptable study to be involved in, with the end of study questionnaire discussed in Chapter 7 highlighting that those in the pKHA group would likely seek

it out again. This finding cannot be underestimated, as the acceptability of an intervention needs to be established before embarking upon a large scale RCT (Craig *et al.* (2008).

## **8.2 Future definitive RCT**

Within the MRC framework for complex interventions (Craig *et al.* 2008), the focus is more upon a treatment's clinical impact as opposed to the 'active ingredient' involved, and so simply put, if an intervention is shown to be effective, whilst being deemed safe and acceptable to any potential participant, it should be adopted. The intervention would then act as the treatment of choice until another intervention has been shown to be more appropriate, yet the work outlined in this chapter can only act as a beginning to understanding the best approach for PPGP.

The placebo literature put forward in Chapter 3 indicates that many factors can influence treatment effect, and it is therefore possible, and perhaps more likely, that it is a combination of factors that lead to successful management of PPGP in the feasibility study. Whether trends observed in Chapter 7 would continue to be found in a larger study remains to be seen, yet because of positive trends and comments by participants, the study in a larger form is vindicated. As discussed in '7.7.10 Future Research', changes would be made to reduce researcher bias by employing research physiotherapists to carry out the intervention, and in addition to the outcome measures adopted in the feasibility study, a general wellbeing outcome measure, such as the EQ-5D, would be added. Prior to its inception, funding to conduct the study would be needed, and an agreement on power of the sample size (either 80 or 90%) in order to display clinically meaningful results. The main aim would be on effectiveness, measuring pain, function and wellbe-

ing, whilst continuing to monitor the integrity of the study through credibility and believability outcomes, all supported by qualitative data derived from the participants. To enhance the importance of the qualitative aspect, more comprehensive data collection and analysis methods could be done using a similar process to that outlined in Chapter 6, but with women who had completed the effectiveness study.

Taking KHA into a larger study, the patient information leaflet would contain the incidence rate and type of adverse events that were experienced in the Chapter 7 study, combined with adverse events reported in other acupuncture studies (Clarkson, O'Mahoney and Jones, 2015). Therefore, it would be indicated that transient adverse events such as minor bleeding at the needle site are expected, but that serious adverse events are unlikely. This would hopefully provide reassurance to practitioners and patients alike that KHA appears to be safe, though with the caveat that further research is warranted.

### **8.3 Further recommendations for future research**

Pregnancy related pelvic Girdle pain is a condition that has gained traction within the research world in the last 10 years. Despite this, there are a number of questions that are yet to be resolved and further research on multiple fronts is needed to advance knowledge beyond the findings of this thesis. Chapter 2 served to highlight that a more specific definition is required to better reflect PPGP as an entity in its own right. The Vleeming *et al.* (2008, p.797) definition focuses upon physical symptoms; '(PPGP) generally arises in relation to pregnancy, trauma and/or osteoarthritis. The pain can be located anywhere around the pelvic girdle, more specifically around the posterior iliac crest and gluteal folds, and/or radiating to the posterior thigh, and to include pain around the symphysis'. This definition applies to pelvic pain across the general population, and whilst it helps to encapsulate pain around the pelvis that is not organ related, it does not

reflect the discussion points and findings presented within this thesis.

#### **8.4 Redefining PPGP**

It would appear from the existing literature, and results displayed in the studies presented within Chapter 6 and 7, that pregnancy can trigger the creation of PPGP, and when pregnancy has completed, it resolves in most cases (Rost *et al.* 2006). Regardless of the physiological causes of PPGP, this consideration lends weight to PPGP as a specific subset of PGP that can be defined in its own right. Additionally, the literature presented in Chapter 2, and findings from the PGQ data in Chapter 7, suggest that PPGP is often accompanied by restrictions to ADL's, and findings from Chapter 6 suggests that this can be accompanied by social restrictions and changes to mood. The current definition by Vleeming *et al.* (2008) is devoid of any psychosocial context, and actually refers to pelvic girdle pain (PGP) in any population, not specific to pregnancy. Perhaps a more accurate definition of PPGP could be: 'primarily symptoms of pain around the pelvic girdle which have manifested as a result of pregnancy, which exclude pathology of the internal organs, impacting upon the biopsychosocial health and physical capabilities of the pregnant woman.' This not only recognises PPGP as an outright entity, but also guides practitioners and researchers alike to what should be considered when planning and implementing its management. However, this would need to achieve consensus from the global clinical and research communities to be considered a valid definition, which the researcher here hopes to achieve through peer reviewed publication or adoption in guidelines such as NICE or European guidelines similar to those of Vleeming *et al.* (2008).

In an ideal world, data would be collected (or already exist) on the usual course of PPGP, in order for a researcher to identify whether an intervention is contributing to

symptom alleviation. However, as interventions such as physiotherapy and acupuncture have been shown to have beneficial effects to symptoms of PPGP (Gutke *et al.* 2015), it would be unethical to include a group that would effectively deny them treatment. From the findings of the feasibility study conducted in Chapter 7, a physiotherapy only group which consists of an initial appointment only, would seem to not allow for enough data collection to make meaningful conclusions for research conducted in the UK. However, findings from the background literature discussion in Chapter 2 on prevalence, risk factors and usual care approaches demonstrates that there is a need for epidemiological research to be produced from the UK for PPGP.

There is clearly a desire from PPGP sufferers to seek health care attention within the UK, as evidenced by the successful recruitment and qualitative comments provided in the end of study questionnaire, both displayed within Chapter 7. Current epidemiological studies, none of which have been conducted in the UK, adopt a variety of inclusion criteria to encompass PPGP, and so if a consensus is reached upon a definition of PPGP, more accurate data could be collected and analysed. There is an opportunity to raise the problem of lacking data in PPGP within the research community, perhaps through peer review publication of the current state of epidemiological studies to stimulate interest in the area. The data collection within an epidemiological study would likely be best placed in the hands of community midwives, who see the vast majority of UK based pregnant women on several occasions throughout their pregnancy. Although this would require feasibility and pilot testing, pregnant women could be asked to complete demographic data alongside self-reported outcome measures of NRS for pain, PGQ and general well-being. This would provide a better understanding of how PPGP affects a wider population, and provide insight into the natural progression of PPGP. At present, because these data are currently unavailable, findings from interventional studies are limited in

that there is not a method of comparing outcomes to usual progression of the condition.

As discussed earlier, the method adopted for the study in Chapter 7 can be used for future larger scale studies with the aim of producing information on whether KHA should be adopted into the management of PPGP. However, further research into acupuncture for PPGP could be extended to direct comparisons between body acupuncture or auricular and KHA. One rationale for providing KHA is that it allows the individual to move freely around the treatment room whilst the needles are in situ, which the body acupuncture approach does not. The researcher here puts forward that because sustained postures, and the moving up and down from a sitting or lying position aggravate PPGP, it maybe that KHA could provide benefit over and above that demonstrated by its body acupuncture counterpart. This would require further investigation, and because it would be impossible to blind women from receiving KHA or body acupuncture, there are two approaches that could be adopted.

First, a pragmatic study which looks not to blind the participants to the group that they are randomised to, but looks to compare whether one group is superior to another. This has been conducted successfully by Thomas, MacPherson and Thorpe (2006) in an acupuncture study for LBP, with the rationale that this more closely resembles standard practice than the procedure of blinding participants to a treatment. It may also yield a smaller dropout rate, as half of the participants would not be randomised to a non-penetrating approach. The other potential method would be to conduct a four-arm study, including penetrating KHA, penetrating body acupuncture, and a non-penetrating approach to each. Either study would have merit in rationale and likely be feasible to run in terms of acceptability, if the recruitment findings displayed in Chapter 7 are considered. In either instance, the continued use of the credibility outcome measure, NRS, PGQ, and



other wellbeing outcome measures such as EQ-5D would be appropriate, with the involvement of qualitative data to gain deeper understanding of participant perception important.

### **8.5 Implications for future practice**

On publication of the work conducted in this thesis, several findings could be taken into practice. The literature review in Chapter 3 highlighted the current strength of evidence for acupuncture in PPGP, and combined with trends observed in Chapter 7, begins to demonstrate acupuncture as an effective approach for PPGP management. However, taking the results for Chapter 7 alone would not be recommended, due to the limitations of a feasibility study and the need for a fully powered trial. If a subsequent fully powered study did replicate findings from Chapter 7, then it may encourage 'reluctant' clinicians, as observed by Waterfield *et al.* (2015), to consider acupuncture for PPGP.

Further aspects from the literature review could impact upon practice, with the discussion on placebo informing practice on what factors influence positive treatment effects. Also, the existing PPGP literature, in combination with the findings from Chapter 6, have led to a new definition for PPGP given in this chapter, which clinicians could use to help identify all issues surrounding PPGP. Additionally, the emphasis on collecting quantitative and qualitative evidence may help clinicians to structure treatment outcome measurement, with the qualitative evidence provided in Chapter 6 and 7 highlighting how PPGP can impact upon a women, and what they would consider to be an effective treatment.

### **8.6 Limitations**

The consensus within the literature displayed in Chapter 2 is that diagnosis of PPGP is

through the use of a battery of physical tests to differentiate from LBPp and internal organ involvement. As Pennick and Liddle (2013) stipulate, despite a general agreement, the most appropriate tests to conduct needs further work. This could be viewed as a limitation to both Chapters 6 and 7, as the inclusion criteria depended upon the identification of PPGP using the measures outlined in Table 1. Although this produces comparability between the research here and existing literature, it is possible that there is a variance in who is considered to have PPGP. By conducting reliability and validity research, it would allow for a more confident statement that women included in any subsequent interventional study suffered with a very similar condition at baseline, and could eventually lead to a better understanding of the PPGP phenomenon.

The studies outlined in Chapter 5 and 7 were both developed, conducted and analysed by the PhD student. This could have led to bias being introduced at any stage, and would be considered a less rigorous trial than if the researcher had been blinded. As part of the PhD process, the researcher here considered the involvement at all stages of the research to benefit the learning process whilst ensuring the experiment was conducted appropriately. In addition, homogenous groups were also not achieved for all dependent variables within Chapter 5, finding age to be different between the groups, though the difference was minimal. However within the larger sample investigated within Chapter 7, all demographic data were homogenous.

The outcome measures adopted in Chapter 5 and 7 are also susceptible to criticism. The believability outcome was developed for this study, and has, therefore, not been measured for validity and reliability. Carifio and Perla (2007) have put forward that the use of a single Likert item is prone to fluctuating responses, reducing its rigour. However, a Likert type item has been used in previous acupuncture research, namely Sherman *et al.*

(2002), so its use is comparable to published work and would seem to be the best available approach to use in the absence of a validated scale for believability. The credibility outcome measure has also not been validated or demonstrated to be reliable specifically for acupuncture studies, yet this is an accepted outcome within acupuncture literature to assess for credibility between penetrating and non-penetrating acupuncture groups. Finally, the PGQ has been shown to be valid and reliable (Grotle *et al.* 2012), though it does require further investigation in large-scale studies for its sensitivity to change.

For the qualitative interviews discussed in Chapter 6, trustworthiness could have been attended to by conducting member checking and further triangulation. Methods such as focus groups could have followed the one to one interviews, which could have given further insight, or clarity, to themes that had been produced. From an ontological perspective, the adoption of pragmatism has influenced the results produced because data analysis was conducted with the feasibility study in mind. To explore the lived experience of PPGP in greater depth, a philosophical standpoint of phenomenology may be more appropriate. However, in keeping with the mixed methods approach and pragmatism, the thematic approach used in chapter 6 was the most appropriate for this study.

## **8.6 Conclusion**

This thesis has met all of its aims surrounding the development of an npKHA approach which is both believable and acceptable, gained an understanding of PPGP as experienced by UK women, and developed a feasibility study for KHA for PPGP. From an originality perspective, this study was the first to investigate the believability of a non penetrating form of KHA, the first UK based study to investigate women's experience of PPGP and the first piece of qualitative work with the lead author and interviewer being male. The original contributions from Phase 3 are that it is the first study to be conducted

using KHA for a pregnancy related condition in the English language and the first study to adopt a mixed methods approach within the UK for an acupuncture study within pregnancy. Finally, it is the first study written in English that has compared pKHA to npKHA for any condition.

This thesis has demonstrated that improving understanding of PPGP can be investigated using a mixed methods methodology. Korean hand acupuncture has not only been considered acceptable for those involved within this study, but is something that individuals would seek out again, particularly those in the penetrating KHA group within Chapter 7. Chapter 5 and 7 have served to highlight the benefits of adopting mixed methods, as the qualitative data provide richer insight into the quantitative findings, such as why participants believed that they had/had not received penetrating KHA. In the wider context, adopting a mixed methods approach for KHA for PPGP has provided evidence that it is an appropriate approach for meeting the standards set by the MRC (Craig *et al.* 2008). Complex interventions, such as KHA, require a thorough understanding and testing of theories before they are implemented on a wider scale. To gain such an understanding, the use of both qualitative and quantitative data is required in order to gain insight into what will work for PPGP. Chapter 7 has served to highlight the importance of feasibility work, as the results can not only provide a firm platform in which to bid for grants to support a definitive RCT, but has highlighted potential flaws with the original design that would be addressed in a future definitive RCT.

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## Appendix 1 – Pelvic Girdle Questionnaire (PGQ)

To what extent do you find it problematic to carry out the activities listed below because of pelvic girdle pain? For each activity tick the box that best describes how you are today

How Problematic is it for you because of your pelvic girdle pain to:	Not at all (0)	To a small extent (1)	To some extent (2)	To a large extent (3)
Dress yourself				
Stand for less than 10 minutes				
Stand for more than 60 minutes				
Bend down				
Sit for less than 10 minutes				
Sit for more than 60 minutes				
Walk for less than 10 minutes				
Walk for more than 60 minutes				
Climb stairs				
Do housework				
Carry light objects				
Carry Heavy objects				
Get up/sit down				
Push a shopping cart				
Run				
Carry out a sporting activity				
Lie Down				
Roll over in bed				
Have a normal sex life				
Push something with one foot				

## Appendix 1 – Pelvic Girdle Questionnaire (PGQ)

How much pain do you experience:	None (0)	Some (1)	Moderate (2)	Considerable (3)
In the morning				
In the evening				

To what extent because of pelvic girdle pain:	Not at all (0)	To a small extent (1)	To some extent (2)	To a large extent (3)
Has your leg or legs given way				
Do you do things more slowly				
Is your sleep interrupted				

## Appendix 2- Adverse event reporting Table

amount of women included in sample	total amount of sessions of penetrating KHA	amount of women effected by at least one adverse event	total amount of transient adverse events that occurred (% of sessions an event occurred in)	total amount of serious adverse events

### Appendix 3- Needle penetration believability outcome measure

1. Please circle the statement which you think best reflects what intervention you received

Definitely True KHA      Probably True KHA      Uncertain      Probably not True KHA      Definitely not True KHA

2. Why do you think you have/have not received Korean Hand Acupuncture?

## **Appendix 4 – Preliminary KHA Patient Information Sheet**

### **Participant Information Sheet**

Development of a placebo approach to Korean Hand Acupuncture

Dear madam

My name is Carl Clarkson, and I am senior lecturer in physiotherapy at Northumbria University and currently undertaking a PhD. I also have an MSc in Acupuncture. As part of this, I would like to invite you to take part in a research study. Before you decide I would like you to understand why the research is being done and what it would involve for you. This should take roughly 5 minutes, although you can contact me on the details below if you have any other questions at all.

#### **Part 1**

What is this study about

This study will try and develop an appropriate placebo approach to Korean Hand Acupuncture (KHA), which could be used within a research trial. A placebo is a procedure which appears like the actual procedure (in this case, true KHA), but has no actual benefit, or active ingredient. This said, people after receiving placebo interventions can report having benefits to their symptoms, especially when the problem is pain. It is important to find a placebo approach to KHA that is very similar to true KHA, so much so that the recipient is not aware if they have had the placebo intervention or true intervention. This would then allow for a future trial into the effectiveness of KHA for pregnancy related pelvic girdle pain to look at whether any treatment effects are greater than just placebo effects. If you decide you would like to be involved, you will be asked to attend a practical room within the university, where you would receive either true KHA, or placebo KHA, and then asked to rate how sure you are that you have received one or the other.

I am doing this study to try and find an appropriate placebo approach to KHA. The results of this study would add to the current body of research into what is an acceptable placebo approach to KHA. It will also help to make sure that a future study into the use of KHA in pregnancy related pelvic girdle pain utilises a placebo KHA intervention that is undistinguishable from the true KHA group.

Why have I been invited?

You have been invited because you are a student, who has similar characteristics

as to those who would be included in a research trial using KHA and placebo KHA. You will be able to take part in this trial if you are all of the following:

Healthy, non pregnant adult woman between 18-40 years of age

Not taking medication for a health problem

No allergies to metal/plastic/sticky plaster

Not contraindicated to acupuncture

What am I being asked to do?

You will be randomly allocated to either the placebo KHA group or the true KHA group. On arrival you will be asked to fill in a sheet outlining some of your characteristics, but to not include your name so data can remain anonymous. You will then be asked to sit on a treatment plinth (the kind you would find in a physiotherapy department or doctor's clinic) and apply a blindfold. I, the researcher, will then administer the placebo or true KHA to the back of your hand, after which you will be asked to remain seated and blindfolded for 30 minutes. Before the blindfold is removed, and after the needle has been removed (if you are in the true KHA group), sticky plasters will be applied to the back of your hand, and you are asked to keep these on for the rest of that day. Finally, after removing the blindfold, you will be asked to complete a scale ranging from definitely received true KHA to definitely did not receive real KHA. This scale will then be emailed to you 1 week from receiving the real/placebo acupuncture to again ask whether you felt you had received placebo or true KHA.

What is Korean Hand Acupuncture?

Korean Hand Acupuncture is a form of therapy in which fine needles are inserted into specific points on the hand.

Is acupuncture safe?

Acupuncture is generally very safe. Serious side effects are very rare – less than one per 10,000 treatments.

Does acupuncture have side effects?

You need to be aware that:

drowsiness occurs in a small number of people, and, if affected, you are advised not to drive immediately after, until the drowsiness has worn off

minor bleeding or bruising occurs after acupuncture in about 3% of acupuncture sessions;

pain during acupuncture occurs in about 1% of acupuncture sessions;



fainting can occur in certain people, particularly at the first acupuncture session.

Is there anything the acupuncturist needs to know?

Apart from the usual medical details, it is important that you let me know:

if you have ever experienced a fit, faint or funny turn;

if you have a pacemaker or any other electrical implants;

if you have a bleeding disorder;

if you are taking anti-coagulants or any other medication;

if you have damaged heart valves or have any other particular risk of infection.

Do I have to take part?

No, it is up to you if you take part. If you decide not to take part then your University studies will not be affected and you will continue with your studies as normal. You can leave the study at any time without giving reason and again this will not affect your studies. You can decide whether to take part after reading this information sheet and/or discussing it with me. If you would like to take part I will ask you to sign a consent form, although you can still decide to leave the study at any time.

What are the possible benefits of taking part?

I cannot promise the study will help you, but the outcome of the study could help our understanding of the placebo effect in KHA, and go toward creating a rigorous study in KHA effects on pregnancy related pelvic girdle pain.

## Part 2

What will happen to me after the study?

Any data collected will be kept anonymous. The study findings will likely be published in a research journal.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part be confidential?

Yes. We (the university research team) will follow ethical and legal practice and all information about you will be handled in confidence. What you say may be published, but this will be anonymised. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

What will happen if I do not want to carry on with the study?

You can withdraw from the study verbally to myself at any time. You can withdraw from the study until 31<sup>st</sup> January 2014, after which the results will be published in a research journal.

What if there is a problem?

If you have a concern about any aspect of the study you can ring me and I will do my best to answer any questions. My telephone is 0191 215 6113. If you remain unhappy and wish to complain, you can do this by contacting Professor Nicola Adams, the research supervisor on 0191 215 6620.

In the event that you do suffer from harm and this is due to somebody's negligence, you may have grounds for a legal claim and compensation from Northumbria University, although you may have to pay legal costs.

Will my taking part in the study be kept confidential?

All information that will be used in the study will be kept under lock and key at Northumbria University and kept strictly confidential. All data will be kept anonymous throughout the study, so that the data collected cannot be traced back to you. The research team are the only people who will view this data. On October 1<sup>st</sup> 2017 all data will be destroyed.

What will happen to the research results of this study?

The results of this study will be used to complete a PhD research study. It may also be published in a research journal. Any research results will be

anonymous. If you wish to know the results of the study then you can by contacting me at the below address and telephone number after October 1<sup>st</sup>, 2017.

Who is organising and funding this study?

I am organising and funding the whole study as part of my PhD thesis.

Who has reviewed this study?

This study has been read and passed favourably by the Northumbria University Faculty Research Ethics Committee

Further contact details

If you would like to know more about this study, please contact me on telephone 0191 215 6113, or my academic supervisor 0191 2156620

If you have any concerns about this study, please contact me on the details below

Yours Faithfully

Carl Clarkson MCSP, MSc. Acupuncture  
Senior Lecturer in Physiotherapy  
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## Appendix 5 -Preliminary KHA consent form

**Appendix 5 -preliminary KHA consent form**  
**(printed on University letter headed paper)**

**Informed Consent Form**  
**Development of a placebo approach to Korean Hand Acupuncture**

Name of Principal Investigator: **Carl Clarkson**  
boxes

Please initial

1. I confirm that I have read and understand the participant information sheet date 11.4.2013 version 1 for the above study. I have had the opportunity to consider the information, ask questions which have been answered fully, and that I do not suffer from any of the contraindications stated in the participant information sheet 12.7.2013 version 2.

YES

☐☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study without giving any reason at any time, without my studies at Northumbria University or legal rights being affected.

☐☐

3. I am happy to be involved in the above study as outlined in participant information sheet 12.7.2013 version 2.

☐☐

4. I understand that any data created from this study will remain in a password protected computer at Northumbria University until 1<sup>st</sup> October 2017, after which the data will be destroyed. All data collected will be anonymous and kept confidential. The only people who will have access to this information are the Principal Investigator and the Principal Investigator's supervisor's.

☐☐

5. The Principal Investigator confirms that the participant is a healthy woman of childbearing age, acupuncture naive, is not contraindicated to receive acupuncture, and has no allergies to metal / plastic / Elastoplast.

☐☐

Name of Participant

Date

Signature

Principal Investigator

Date

Signature

When completed: 1 copy for participant, 1 copy for Principal Investigator (site file)

## Appendix 6 - preliminary KHA Demographics form

Age	
Marital Status	
Occupation (full time/part time)	
Highest level of education (GCSE, A-level, degree etc)	
Hours per week that you currently exercise	

## Appendix 7 - Acupoint location

Acupoint Name	Acupoint Location	Needle gauge/length	Needle Manufacturer	Needle depth	Needle retention time	Needle stimulation
I19 Bilateral	5 mm lateral to B7, dorsal aspect	0.25m m/13mm	Herb Prime	5mm	30 mins	nil
I20 Bilateral	5 mm below I19, dorsal aspect	0.25m m/13mm	Herb Prime	5mm	30 mins	nil
I21 Bilateral	5mm below I20 dorsal aspect	0.25m m/13mm	Herb Prime	5mm	30 mins	nil
I38 Bilateral	5 mm below centre of little finger nail bed	0.25m m/13mm	Herb Prime	5mm	30 mins	nil
B5 Bilateral	5 mm above transverse wrist crease, in line with middle finger, dorsal aspect	0.25m m/13mm	Herb Prime	5mm	30 mins	nil
B6 Bilateral	5 mm below B7	0.25m m/13mm	Herb Prime	5 mm	30 mins	nil
B7 Bilateral	Mid way between middle MCP and transverse crease, dorsal aspect	0.25m m/13mm	Herb Prime	5mm	30 mins	nil
H2 Bilateral	5mm below middle of index finger nail bed	0.25m m/13mm	Herb Prime	5 mm	30 mins	nil

## **Appendix 8 - preliminary KHA raw qualitative data**

### Believed they had received penetrating KHA

#### Non-penetrating KHA

Sharp needle like sensation

Needle being inserted

Needle marks

Tingling sensation

The feeling when being taken out

Pulsing sensation once needles were inserted

#### Penetrating KHA

Felt relaxed during treatment

Tingling sensation

Heavy and achy

Hands stiffened up

Sensation similar to what participant had heard it likely to be

Feeling of needles/sharp sensation

Weird shooting pains

Heard needles being removed

Feeling sleepy

Could feel needles wobbling

Muscle twitching

Heard packaging

## Appendix 8 - preliminary KHA Raw Qualitative data

### Uncertain if received penetrating KHA

#### Non-penetrating KHA

No side effects

Felt no pain

Felt different on each hand

#### Penetrating KHA

Unsure if felt needles

No side effects

### Believed they had not received penetrating KHA

#### Non-penetrating KHA

Didn't feel any different and would have expected to

Didn't feel like needles were going in/coming out of hands

No red marks next day

#### Penetrating KHA

Didn't feel release after needles were removed

Would have expected symptoms to last



## Appendix 9 -Chapter 6 Patient Information Sheet

### Participant Information leaflet

Dear madam

My name is Carl Clarkson, and I am Senior Lecturer in Physiotherapy at Northumbria University and currently undertaking a PhD. I would like to invite you to take part in a research study. Before you decide, I would like you to understand why the research is being done and what it would involve for you. This should take roughly 5 minutes, although you can contact me on the details below if you have any other questions at all.

### Part 1

This study is about what pregnant women's views are surrounding Pregnancy related Pelvic Girdle Pain (PPGP). If you decide you would like to be involved, you will be asked to take part in a one to one interview within the physiotherapy department, where I will ask your views on PPGP.

#### The purpose of the study

I am doing this study to try and gain an understanding as to what is considered to be the main issues surrounding PPGP. The results of this study will help to make sure that a future study into the use of acupuncture in PPGP looks at the issues that are most important to those suffering with PPGP.

#### Why have I been invited?

You have been invited because you have been referred to physiotherapy for help with your symptoms of PPGP. You will be able to take part in this trial if you can say yes to all of the following:

Have given consent (You will be given a form to sign if you wish to take part)

Have been diagnosed with PPGP

pregnant

2<sup>nd</sup>- 3<sup>rd</sup> Trimester

Single pregnancy

English as first language

# Part 1

Do I have to take part?

No, it is up to you if you want to take part. If you decide not to take part then your medical care will not be affected and you will continue with your physiotherapy. You can leave the study at any time without giving reason and again this will not affect the standard of your medical care. You can decide whether to take part after reading this information sheet and discussing it with your physiotherapist or me, the researcher. If you would like to take part I will ask you to sign a consent form, although you can still decide to leave the study at any time.

What will happen to me during the study?

During the study you will be asked to attend an interview. It will be located at the women's health physiotherapy department. I will be there, and will ask you questions on your experience surrounding PPGP. To make it clear, I am interested in your experience of the condition, not how much medical knowledge you have. There are some questions that I would like to ask however these are not set in stone, and so you will be free to talk about what is important in your eyes. There will be a digital voice recorder to record your responses, this is to aid me when I write up the discussion we have had. This interview is expected to be a relaxed atmosphere, with refreshments provided throughout. It is expected that the interview will last approximately 1 hour.

What are the possible side effects of taking part?

There are no side effects anticipated, however, if the discussion raises any concerns, your physiotherapist will be happy to help.

What are the possible benefits of taking part?

I cannot promise the study will help you, but the outcome of the discussions could help our understanding of PPGP and inform future research.

What will happen to me after the study?

Anything you say will be kept anonymous. The interview findings will likely be published in a research journal. Your medical care will not be affected by your attendance to this group.

If the information in Part 1 has interested you and you are considering being involved, please read the additional information in Part 2 before making any decision.

## Part 2

What will happen if I do not want to carry on with the study?

You can withdraw from the study verbally to myself at any time, even after you have completed the interview. You can withdraw from the study until 1<sup>st</sup> August 2014, after which the results will be published in a research journal. Any data produced from our interview will be destroyed on 1<sup>st</sup> October 2017, after my PhD has finished.

What if there is a problem?

If you have a concern about any aspect of the study you can ring me and I will do my best to answer any questions. My telephone is 0191 215 6113. If you remain unhappy and wish to complain, you can do this by contacting the Patient Advice and Liaison Service (PALS) on telephone 0800 0920084.

In the event that you do suffer from harm and this is due to somebody's negligence, you may have grounds for a legal claim and compensation from Northumbria University, although you may have to pay legal costs.

Will my taking part in the study be kept confidential?

Yes. We (myself, the research team at this trust and the university research team) will follow ethical and legal practice and all information about you will be handled in confidence. After the face to face interview the recording will be typed up onto a computer and in the process any information that could identify you will be removed. Your personal details will be kept separately from the record of the interview which will be held on a password protected computer at the University. If the research is presented in an academic journal or at a conference I might quote something you said during the interview; however your name or any information that might identify you will not be included. Your responses during the interview will not be kept with your personal details. No personal information will be passed on to any medical professionals from the interviews. The research team (me and my two PhD supervisor's) team are the only people who will view this information.

Involvement of your GP and midwife

If you decide to take part in the trial your GP and midwife will be informed of your involvement via letter, if you consent for me to do so. The letter will explain to your GP and midwife that you have been invited to and consented to taking part in this study, and that if the GP or midwife has any questions that they can contact me.

What will happen to the research results of this study?

The results of this study will help to form a study looking at the effects of a treatment modality for PPGP, and be used to complete a PhD research study. It may also be published in a research journal. Any research results will be anonymous. If you wish to know the results of the study then you can by contacting me at the below address and telephone number after October 1st, 2017, or leave your contact details on the end of the consent form.

Who is organising and funding this study?

I am organising and funding the whole study as part of my PhD thesis.

Who has reviewed this study?

All research in the NHS is checked by a group of independent people called the NHS Research and Ethics committee to protect your interests. This study has also been read and passed favourably by the Northumbria University Ethics Panel, the Newcastle Upon Tyne hospitals foundation trust research and development department and Newcastle and North Tyneside 1 Research Ethics Committee.

Further contact details

If you would like to know more about this study, please contact me on telephone 0191 215 6113, or my academic supervisor 0191 215 6620

If you have any concerns about this study, please contact me on the details below

Yours Faithfully

Carl Clarkson MCSP, MSc. Acupuncture  
Senior Lecturer in Physiotherapy  
Faculty of Health and Life Sciences  
Northumbria University  
0191 215 6113  
[carl.clarkson@northumbria.co.uk](mailto:carl.clarkson@northumbria.co.uk)

## **Appendix 10 -Chapter 6 interview schedule**

What is it like to be pregnant?

Is it what you expected?

What does the diagnosis of PPGP mean to you?

Is pain the main problem?

How would you describe PPGP?

To yourself, before you developed it

To a female friend considering becoming pregnant

To a person who has been pregnant but not experienced pelvic girdle pain

What do you think other people who do not have PPGP think about it?

For example health professionals?

Close friends/family?

Work colleagues/employers?

How does your PPGP affect your day-to-day life?

Does it restrict you?

Is pain the main problem?

Is it something you would seek medical treatment for?

Do you have any concerns about PPGP?

How do you manage your PPGP?

Do you feel it has helped?

How do you feel about taking medication?

How do you feel about performing exercises?

What options are you aware of that may help with your PPGP?

Access to health professionals within/outside of the NHS

Are you aware of an approach that has not been suggested by a health professional

Is there anything you have found that does not help with your PPGP

Is there anything that has made it worse?

Is there any advice you would give others?

What would be an “effective” treatment for you?

Reduction/removal of some symptoms?

Reduction/removal of all symptoms?

Feeling better in one’s self?

What would be an “ineffective” treatment to you?

Too time consuming?

Demonstrated small affects

Gave only short lived benefits

Reduction in pain only?

Do you think this tool would accurately reflect the issues that you are dealing with? (*Shown the PGQ outcome measure*)

Is there anything on there that is irrelevant to you?

Is there anything on the outcome measure that should be changed?

Is it easy to follow/us

## Appendix 11 -Chapter 6 raw data

<p>impact on ADL's</p>	<p>can't get up the stairs or like I don't sleep for like a week</p> <p>you get really tired as well... I wake up 7 or 8 times during the night</p> <p>I'll maybe get out well this week I've been out twice which is like in a wheelchair</p> <p>am normally like a social active person and it has made me the most miserable anti-social person I don't want to speak to anyone I don't want to go anywhere cos I'm in too much pain</p> <p>everything that you found was normal before now isn't because you've got a big bump in the way and carrying all this extra weight it's just hard (this is likely to be because of pregnancy rather than PGP)</p> <p>I couldn't push the trolley</p> <p>getting up in the morning is one of the biggest things</p> <p>I don't change our son on the floor anymore because I can't physically bend over anyway my bump won't let me</p> <p>I'm realising having to realise what you're doing instead of just ignoring it.</p> <p>I can't walk as far [ok] which is awful from being such an active person..... admit to myself really right your pregnant, you can't walk 5 miles anymore...I sort of try not to go as far</p> <p>I'm having to take slower steps..... I haven't done it for a while and church is another one we go to church on Sunday and I have to play that by ear it's literally on a Sunday if I can if I get up and I feel I'm ok to walk an hour about 45 minutes it takes us to walk there</p> <p>have to know how to roll over because that really really hurts</p> <p>dressing myself can be really really difficult. I can't stand for too long</p>
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## **Appendix 12 - Clarkson, C.E., O'Mahony, D., Jones, D.E. (2015)**

### **“Adverse event reporting in studies of penetrating acupuncture during pregnancy: a systematic review’ *Acta Obstetrica Gynecologica Scandinavica* 94 (5) (abstract)**

*Background* Acupuncture within pregnancy has been investigated frequently, often finding acupuncture to be more effective than standard care. However, the adverse event severity, types and occurrence are unclear. *Objective* To investigate the quality of reporting adverse events and to attempt to identify occurrence, type and severity of adverse events in acupuncture and non-acupuncture groups. *Data sources* MEDLINE, CINAHL, Allied and Complementary Medicine Database, and Physiotherapy Evidence Database (PEDro) were searched for relevant studies between 2000-2013. *Study selection* Seventeen studies utilizing penetrating acupuncture and making comment on adverse events experienced were included. Quality appraisal of the selected papers was performed using either the PEDro scale or the Downs and Black checklist. Quality of reporting was evaluated against STRICTA and CONSORT guidelines, with data on adverse events extracted in accordance with CONSORT and Good Clinical Practice adverse event guidelines. *Results* Overall quality of reporting of adverse events was poor, with information describing the adverse events often lacking in detail. A number of trends were noted: adverse events occurring within a treatment session was 3%-17% in the acupuncture groups and 4-25% in the non-acupuncture groups. The percentage of women affected by an adverse event was between 14%-17% in the acupuncture groups and 15-19% in non-acupuncture groups. *Conclusions* Adverse event reporting within acupuncture trials is generally poor. Trends noted were that adverse events do occur, but would appear to be largely minor and comparable to non-acupuncture related interventions.

The full text can be found at: [onlinelibrary.wiley.com/doi/10.1111/aogs.12587/abstract](http://onlinelibrary.wiley.com/doi/10.1111/aogs.12587/abstract)



## Appendix 13 -Qualitative comments made in pKHA group

Participant	General effects	Effects on symptoms	Other comments
1	felt sleepy	felt worse on day of 1st session pain much easier since first session	felt baby kicking during session
2	relaxed immediately after/rest of day	pain less relief very good 2/7 after each session	
3	slept well		
4	slept well 2/7 relaxed	able to do more pain has not progressed pain easier overall	
5		1/7 relief	very little movement of baby - had scan, no problems
6	relaxed	doing more activity pain up and down	felt baby moving
7	relaxed sleeping improved	no change to pain able to walk dog for 20 mins feels acupuncture has made a significant improvement to her life	diagnosed with gestational diabetes
8		working much easier end of study reported pain not as bad after work and it wasn't waking her up as much	pt queried whether they had felt needle fall out
9		several hours relief only - though it is worth it	
10	relaxed and sleepy on day	posterior pain reduced significantly	
11	sleep a little easier	pain relief for several hours easier to get on and off bed now	
12	sleeping much easier for 3-4 days		
13		significantly easier, able to roll over in bed much easier feels it has prevented from getting worse doing more day to day activities which believes has aggravated pain	

### Appendix 13 -Qualitative comments made in pKHA group

Participant	General effects	Effects on symptoms	Other comments
14	slept a little better  headaches have been easier	struggled with bending forward  symptoms have remained constant throughout  been on feet more at work  no longer taking painkiller	
15	sleeping better  burst of energy  increase in tiredness	pain easier on occasion  pain worse first thing then eases off after a couple of minutes  very little pain throughout night and first thing in morning	
16		feels stiff after last session  pain a little easier  feeling much better compared to last week	
17		feels it helps with short term management of pain  only 1 episode of pain since last session	Braxton hicks, no waters broken and checked with mid-wife
18		pain only present when walking long distances or lifting heavy objects  feels pain has improved dramatically	

## Appendix 14 - Qualitative comments made in npKHA group

Participant	General effects	Effects on symptoms	Other comments
19	sleeps well on day of treatment	on day of acup has good relief	
20		continued to get worse pain	
21	struggling to sleep	not doing as many ADLs now pain up and down	
22	sleeping better	no change to resting pain, pain on moving easier	
23		feels treatment is working	

## **Appendix 15 - End of study questionnaire**

Why did you enrol onto the study initially?

What made you continue to be involved in the study?

Would you seek similar treatment in the future?

Was there anything during the trial that you found inconvenient/annoying?

Do you feel the information given to you prior to enrolling onto the trial was accurate?

Is there any additional information you think should have been included prior to you enrolling?

What recommendations would you make to researcher's looking to do this trial again?

## Appendix 16 -Participant Information Sheet Chapter 7

Dear madam

My name is Carl Clarkson, and I am Senior Lecturer in Physiotherapy at Northumbria University and currently undertaking a PhD, and I would like to invite you to take part in a research study. Before you decide, I would like you to understand why the research is being done and what it would involve for you. This should take roughly 5 minutes, although you can contact me on the details below if you have any other questions at all.

### Part 1

This study will try to find if it is feasible to investigate Korean Hand Acupuncture (KHA) on a large scale, and the effects KHA has on pregnancy related pelvic girdle pain (PPGP). If you decide you would like to be involved, you will be asked to sign a consent form on enrolment onto the study. Once enrolled, you may receive standard physiotherapy, standard physiotherapy plus fake KHA, or standard physiotherapy plus true KHA.

#### The purpose of the study

I am doing this study to try and find the best to investigate KHA effects on PPGP. This means that this study will look at how many people would be needed in a larger trial, how many people are interested in taking part, to look at the appropriateness of the methods used, and to see if any effects of KHA are noted. It would be hoped that this study will help inform future research into PPGP.

#### Why have I been invited?

You have been invited because you have been diagnosed by your physiotherapist as having PPGP, and that you wish to seek treatment for the symptoms. You are able to take part if you:

Give informed Consent

Single pregnancy

Have no major health issues

Pregnant with PPGP

2<sup>nd</sup>-3<sup>rd</sup> Trimester

Are safe to do exercise and receive acupuncture (your physiotherapist will check for this in your physiotherapy appointment)

Do I have to take part?

No, it is up to you if you take part. If you decide not to take part then your medical care will not be affected and you will continue with your care as normal. You can leave the study at any time without giving reason and again this will not affect your medical care. You can decide whether to take part after reading this information sheet and/or discussing it with your physiotherapist. If you would like to take part your physiotherapist will ask you to sign a consent form, although you can still decide to leave the study at any time.

What will happen to me during the study?

If you decide you want to be involved, your physiotherapist will ask you a few questions to make sure it is safe for you to receive standard physiotherapy and KHA. A letter will also be sent to your GP and Midwife to inform them of your enrolment to the study. If this is ok, you will then be asked to sign a consent form - this is called informed consent, and this is to ensure you know exactly what the study is about and you are happy to be involved. Feel free to ask your physiotherapist if you are still not sure. Once you have signed your consent form and completed the questions, you will be randomly assigned to one of three groups - standard physiotherapy, standard physiotherapy plus fake KHA, or standard physiotherapy plus true KHA. You will not be told if you are receiving fake KHA or true KHA. Standard physiotherapy, in any of the three groups may entail - advice, exercises, hands on treatment. You will then be asked to answer questions regarding your symptoms, and record the answers on two separate forms.

If you are assigned to one of the KHA groups, you will receive standard physiotherapy in addition to KHA. If you are to receive KHA, you will be asked to sit on a treatment bed, and blindfolded. The physiotherapist will then administer the fake or true KHA to the back of your hand, of which you will likely feel 9 small pricking sensations on each hand. You will then be asked to sit for 30 minutes, after which time you will feel the physiotherapist apply pressure to the back of your hand, remove the needles and then apply sticky elastoplasts. You will be asked to keep these in place for 24 hours.

You will be asked to return to the clinic 6 times within an 8 week period if in one of the KHA groups. You will be again asked to answer the questions (the same as given to you originally regarding your symptoms) ,after your 3<sup>rd</sup> session and after your 6<sup>th</sup> session. If you are in the standard physiotherapy group, you may only have one session in contact with the physio, with a follow up telephone call at 3 weeks and 6 weeks after your initial appointment to answer questions you were asked at your original appointment. This is considered standard physiotherapy practice. Either on your 6<sup>th</sup> session if in a KHA group, or 6 weeks after your initial appointment if in the standard care only group, you will be asked to complete a short questionnaire asking you what it felt like to

be involved in the study.

At any point you will be able to ask for assistance or to stop the intervention.

What is Korean Hand Acupuncture?

Korean Hand Acupuncture is a form of therapy in which fine needles are inserted into specific points on the hand.

Is acupuncture safe?

Acupuncture is generally very safe. Serious side effects are very rare - less than one per 10,000 treatments.

Does acupuncture have side effects?

You need to be aware that:

drowsiness occurs after treatment in a small number of patients, and, if affected, you are advised not to drive;  
minor bleeding or bruising occurs after acupuncture in about 3% of treatments;  
pain during treatment occurs in about 1% of treatments;  
symptoms can get worse after treatment (less than 3% of patients). You should tell your physiotherapist about this, but it is usually a good sign;  
fainting can occur in certain patients, particularly at the first treatment.

Is there anything your practitioner needs to know?

Apart from the usual medical details, it is important that you let your practitioner know:

if you have ever experienced a fit, faint or funny turn;  
if you have a bleeding disorder;  
if you are taking anti-coagulants or any other medication;  
if you have damaged heart valves or have any other particular risk of infection.

The research within acupuncture to date has not found acupuncture to carry any increased risk to baby or mother.

What are the possible benefits of taking part?

I cannot promise the study will help you, but the outcome of the study could help our understanding of KHA's effects on PPGP and inform future research. It is anticipated that regardless of which group you are assigned to, you will have some easing of symptoms. Receiving KHA, either fake or true, may have additional benefits to physiotherapy alone.

What will happen to me after the study?

Any data collected will be kept anonymous. The study findings will be published in a research journal.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part be confidential?

Yes. We (myself, the research team at this trust and the university research team) will follow ethical and legal practice and all information about you will be handled in confidence. What you say may be published, but this will be anonymised. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

## Part 2

What if new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, your physiotherapist will tell you and discuss whether you should continue in the study.

What will happen if I do not want to carry on with the study?

You can withdraw from the study at any point in time, even if you have finished the study. You can speak to your physiotherapist or me about this.

Involvement of your GP and midwife

If you decide to take part in the trial your GP and midwife will be informed of your involvement via letter, if you consent for me to do so. The letter will explain to your GP and midwife that you have been invited and consented to taking part in this study, and that if the GP or midwife has any questions that they can contact me.

What if there is a problem?

If you have a concern about any aspect of the study you can ring me and I will



do my best to answer any questions. My telephone is 0191 215 6113. If you remain unhappy and wish to complain, you can do this by contacting the Patient Advice and Liaison Service (PALS) on telephone 0800 0920084. In the event that you do suffer from harm and this is due to somebody's negligence, you may have grounds for a legal claim and compensation from Northumbria University, although you may have to pay legal costs.

Will my taking part in the study be kept confidential?

All information that will be used in the study will be kept under lock and key at Northumbria University and kept strictly confidential. All data will be kept anonymous throughout the study, so that the data collected cannot be traced back to you. The research team are the only people who will view this data. On October 1<sup>st</sup> 2017 all data will be destroyed.

What will happen to the research results of this study?

The results of this study will be used to complete a PhD research study. It may also be published in a research journal. Any research results will be anonymous. If you wish to know the results of the study then you can by contacting me at the below address and telephone number after October 1<sup>st</sup>, 2017.

Who is organising and funding this study?

I am organising and funding the whole study as part of my PhD thesis.

Who has reviewed this study?

All research in the NHS is checked by a group of independent people called the NHS Research and Ethics committee to protect your interests. This study has been read and passed favourably by the Northumbria University Ethics Panel and Newcastle upon Tyne foundation hospitals research and development department.

Further contact details

If you would like to know more about this study, please contact me on telephone 0191 215 6113, or my academic supervisor 0191 215 6620. If you

have any concerns about this study, please contact me on the details below.

Yours Faithfully

Carl Clarkson MCSP, MSc. Acupuncture  
Senior Lecturer in Physiotherapy  
Faculty of Health and Life Sciences  
Northumbria University  
0191 215 6113  
07799433528

## Appendix 17 - Consent form Chapter 7

### Informed Consent Form

Name of Chief Investigator: **Carl Clarkson**

Please initial boxes

I confirm that I have read and understand the participant information sheet date 26.3.2014 version 2 for the above study. I have had the opportunity to consider the information, ask questions which have been answered fully.

YES

NO

☐☐

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐☐

I agree to my GP & midwife being informed of my participation in the study.

☐☐

I am willing to participate in the study outlined in the participant information leaflet dated 26.3.2014 version 2.

☐☐

I understand that any data created from this study will remain under a locked filing cabinet until 1<sup>st</sup> October 2017, after which the data will be destroyed. All data collected will be anonymous and kept confidential. The only people who will have access to this information are the Chief Investigator and the Chief Investigator's supervisor's.

☐☐

The Chief Investigator confirms that the participant meets the inclusion criteria of this study.

☐☐

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Chief Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed: 1 copy for participant, 1 copy for Chief Investigator (site file), 1 copy to be kept in physiotherapy notes

## Appendix 18 -General demographics Chapter 7

<b>Age</b>	
<b>Marital Status</b>	
<b>Occupation</b> (full time / part time)	
<b>Highest level of education</b> (GCSE, A-level, degree etc)	
<b>Did you use the contraceptive pill in the last year before falling pregnant</b> (yes / no)	
<b>Hours per week that you currently exercise</b>	
<b>Weeks gestation / Expected delivery date</b>	
<b>Period of time with PPGP</b>	

## Appendix 19 -Feasibility outcome measure Chapter 7

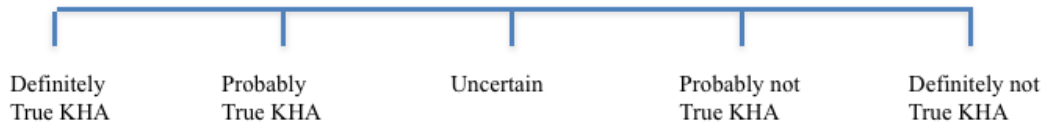
1. On a scale of 0-10, 0 being no pain whatsoever, 10 being the worst pain you could ever experience, where would you say your pain is at present (please circle the number below)?



2. On a scale of 0-10, 0 being no pain whatsoever, 10 being the worst pain you could ever experience, where would you say your pain has been for the last week (please circle the number below)?



3. Please circle the statement which you think best reflects what intervention you received



4. Why do you think you have / have not received Korean Hand Acupuncture?

5. How many times have you received acupuncture, including this session?

## **Appendix 20 -Credibility Scale**

1. How confident do you feel that this treatment can alleviate your complaint?

**Strongly Agree   Mostly Agree   Uncertain   Mostly Disagree   Strongly Disagree**

2. How confident would you be in recommending this treatment to a friend who suffered from similar complaints?

**Strongly Agree   Mostly Agree   Uncertain   Mostly Disagree   Strongly Disagree**


3. How logical does this treatment seem to you?

**Strongly Agree   Mostly Agree   Uncertain   Mostly Disagree   Strongly Disagree**

4. How successful do you think this treatment would be in alleviating other complaints?

**Strongly Agree   Mostly Agree   Uncertain   Mostly Disagree   Strongly Disagree**

## Appendix 21 -NRES letter of agreement for study extension

  
**Health Research Authority**  
NRES Committee North East - Newcastle & North Tyneside 1  
Jarrow Business Centre  
Room 002  
Viking Industrial Park  
Riding Mill Road  
Jarrow  
NE32 3DT  
Tel: 0191 428 3384

22 October 2014

Mr Carl Clarkson  
Senior Lecturer  
Northumbria University  
G207 Coach Lane Campus East  
Benton  
Newcastle Upon Tyne  
NE7 7XA

Dear Mr Clarkson

**Study title:** The effectiveness of Korean Hand Acupuncture for pregnancy related pelvic girdle pain (PPGP)  
**REC reference:** 14/NE/0069  
**Protocol number:** 1  
**Amendment number:** Minor Amendment - study extension, 15/10/14  
**Amendment date:** 15 October 2014  
**IRAS project ID:** 135428

Thank you for your letter of 15 October 2014, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

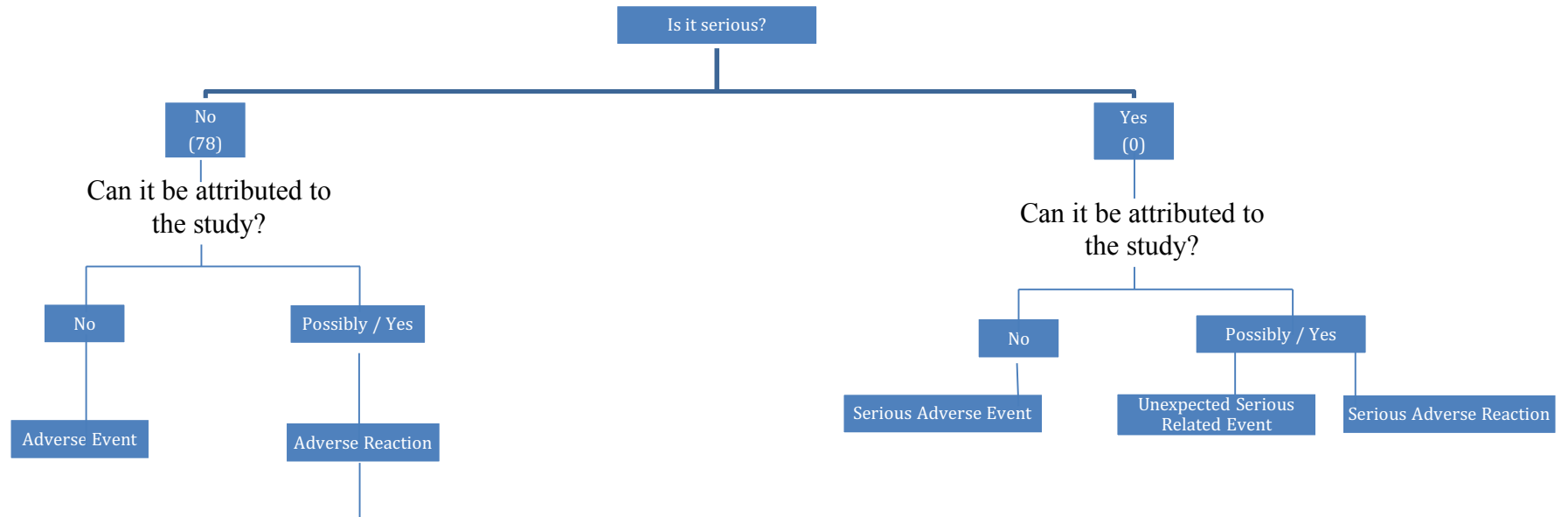
Document	Version	Date
Notice of Minor Amendment	Minor Amendment - study extension, 15/10/14	15 October 2014
Other (Phase 3 Extension Request)	C. Clarkson	14 October 2014
Other (PI Supporting Letter)	J. Ellis	14 October 2014

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for

A Research Ethics Committee established by the Health Research Authority

## Appendix 22- Adverse Events reported in pKHA and npKHA



**Bleeding at needle insertion site** (23 of the 24 participants in the pKHA group, 73 times in total)  
**Bruising/Ecchymosis** (one participant after one session, pKHA group)  
**Increase in symptoms immediately after session** (one participant in two sessions, npKHA group)  
**Nausea** (one participant after one session, pKHA group)  
**Itchiness** (one participant after one session, pKHA group)

## Appendix 23 – Normality tests

Variable	Statistical significance (Kolmogorov-Smirnov)
NRS at present baseline	P=0.001
NRS at present mid point	P=0.009
NRS at present final point	P=0.004
NRS average over last week baseline	P=0.000
NRS average over last week mid point	P=0.000
NRS average over last week final point	P=0.002
Age	P=0.2
Average exercise	P=0.2
Gestation on enrolment	P=0.003
Gestation of PPGP start point	P=0.2



## Appendix 24 – NRES letter of approval for Chapter 6 and 7

  
**Health Research Authority**  
**NRES Committee North East - Newcastle & North Tyneside 1**  
TEDCO Business Centre  
Room 002  
Rolling Mill Road  
Jarrow  
NE32 3DT

Telephone: 0191 428 3565

2 April 2014

Mr Carl Clarkson  
Senior Lecturer  
Northumbria University  
G207 Coach Lane Campus East  
Benton  
Newcastle upon Tyne  
NE7 7 XA

Dear Mr Clarkson

<b>Study title:</b>	<b>The effectiveness of Korean Hand Acupuncture for pregnancy related pelvic girdle pain (PPGP)</b>
<b>REC reference:</b>	<b>14/NE/0060</b>
<b>Protocol number:</b>	<b>1</b>
<b>IRAS project ID:</b>	<b>135428</b>

Thank you for your notification of 31 March 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Ms Gillian Mayer, [nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net](mailto:nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net)

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **Favourable** ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

### Ethical review of research sites

#### NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

## Appendix 25 – Trust Research and Development approval

SS/SB/HO

07 April 2014

Trust R&D Project: 6894  
Title of Project: The effectiveness of Korean Hand Acupuncture for Pregnancy related Pelvic Girdle Pain  
Principal Investigator: [REDACTED]  
Number of patients: 72  
Funder (proposed): Directorate Funding & Own Account  
Sponsor (proposed): Northumbria University  
REC number: 14/NE/0060  
IRAS Project Code: 135428  
First participant to be recruited by: 07 May 2014

After completion the necessary risk and site assessments for the above research project, [REDACTED] grants NHS Management Permission for this research to take place at this Trust dependent upon:

- (i) you, as Principal Investigator, agreeing to comply with the Department of Health's Research Governance Framework for Health and Social Care, and confirming your understanding of the responsibilities and duties of Principal Investigators by signing the Investigator Responsibilities Document. A copy of this document will be kept on file within the Joint Research Office.
- (ii) you, as Principal Investigator, ensuring compliance of the project with all other legislation and guidelines including Caldicott Guardian approvals and compliance with the Data Protection Act 1998, Health and Safety at Work Act 1974, any requirements of the MHRA (eg CTA, EudraCT registration), and any other relevant UK/European guidelines or legislation (eg reporting of suspected adverse incidents).
- (iii) where applicable, you, as Principal Investigator, should also adhere to the GMC supplementary guidance *Good practice in research* and *Consent to research* which sets out the good practice principles that doctors are expected to understand and follow if they are involved in research – see [http://www.gmc-uk.org/guidance/ethical\\_guidance/5991.asp](http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp)

**The NIHR requires NHS organisations to recruit patients to CLRN Portfolio studies within 30 days from the date of this letter. The 30 day deadline for recruiting the first patient is therefore 07 May 2014.**

Please note: the Department of Health 70 day bench mark requires recruitment within 70 days of a valid SSI submission. Therefore, recruiting within the NIHR 30 day target will ensure compliance with both targets.